UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2020

001-12934
(Commission file number)

ImmuCell Corporation

(Exact name of Registrant as specified in its charter)

Delaware	**01-0382980**
(State of incorporation)	**(I.R.S. Employer Identification No.)**
56 Evergreen Drive, Portland, Maine	**04103**
(Address of principal executive office)	**(Zip Code)**

Registrant's telephone number: (207) 878-2770

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, par value $0.10 per share
(Title of class)

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☑

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes ☑ No ☐

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☑ Emerging growth company ☐

Indicate by check mark whether the Registrant has filed a report or an attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 USC 7262(b)) by the independent registered public accounting firm that prepared or issued its audit report. Yes ☐ No ☑

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of the voting and non-voting common equity held by non-affiliates at June 30, 2020 was approximately $29,521,000 based on the closing sales price on June 30, 2020 of $4.73 per share.

The number of shares of the Registrant's common stock outstanding at March 19, 2021 was 7,220,836.

Documents incorporated by reference: Portions of the Registrant's definitive Proxy Statement to be filed in connection with the 2021 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

ImmuCell Corporation
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December 31, 2020

PART I

ITEM 1 – BUSINESS

Cautionary Note Regarding Forward-Looking Statements (Safe Harbor Statement):

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, any statements relating to: our plans and strategies for our business; projections of future financial or operational performance; the timing and outcome of pending or anticipated applications for regulatory approvals; factors that may affect the dairy and beef industries and future demand for our products; the extent, nature and duration of the COVID-19 pandemic and its consequences, and their direct and indirect impacts on the Company's production activities, operating results and financial condition and on the customers and markets the Company serves; the scope and timing of ongoing and future product development work and commercialization of our products; future costs of product development efforts; the estimated prevalence rate of subclinical mastitis and producers' level of interest in treating subclinical mastitis given the current economic and market conditions; the expected efficacy of new products; estimates about the market size for our products; future market share of and revenue generated by current products and products still in development; our ability to increase production output and reduce costs of goods sold; the future adequacy of our own manufacturing facilities or those of third parties with which we have contractual relationships to meet demand for our products on a timely basis; the impacts of backlogs on customer relationships; the anticipated costs of (or time to complete) planned expansions of our manufacturing facilities and the adequacy of our funds available for these projects; the continuing availability to us on reasonable terms of third-party providers of critical products or services; the robustness of our manufacturing processes and related technical issues; estimates about our production capacity, efficiency and yield, which are highly subject to biological variability and the product format mix of our sales; the future adequacy of our working capital and the availability and cost of third-party financing; future regulatory requirements relating to our products; future expense ratios and margins; future compliance with bank debt covenants; costs associated with sustaining compliance with current Good Manufacturing Practice (cGMP) regulations in our current operations and attaining such compliance for the facility to produce the Nisin Drug Substance; our effectiveness in competing against competitors within both our existing and our anticipated product markets; the cost-effectiveness of additional sales and marketing expenditures and resources; anticipated changes in our manufacturing capabilities and efficiencies; the value of our net deferred tax assets; projections about depreciation expense and its impact on income for book and tax return purposes; anticipated market conditions; and any other statements that are not historical facts. Forward-looking statements can be identified by the use of words such as "expects", "may", "anticipates", "aims", "intends", "would", "could", "should", "will", "plans", "believes", "estimates", "targets", "projects", "forecasts", "seeks" and similar words and expressions. In addition, there can be no assurance that future developments affecting us will be those that we anticipate. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to difficulties or delays in development, testing, regulatory approval, production and marketing of our products (including the **First Defense**® product line and **Re-Tain™**), competition within our anticipated product markets, customer acceptance of our new and existing products, product performance, alignment between our manufacturing resources and product demand (including the consequences of backlogs or excess inventory buildup), our reliance upon third parties for financial support, products and services, changes in laws and regulations, decision making and delays by regulatory authorities, currency values and fluctuations and other risks detailed from time to time in filings we make with the Securities and Exchange Commission (SEC), including our Quarterly Reports on Form 10-Q, our Annual Reports on Form 10-K and our Current Reports on Form 8-K. Such statements involve risks and uncertainties and are based on our current expectations, but actual results may differ materially due to various factors, including the risk factors summarized under **PART I: ITEM 1A – RISK FACTORS** of this Annual Report on Form 10-K and uncertainties otherwise referred to in this Annual Report.

Summary

ImmuCell Corporation was founded in 1982 and completed an initial public offering of common stock in 1987. After achieving approval from the Center for Veterinary Biologics, U.S. Department of Agriculture (USDA) to sell **First Defense**® in 1991, we focused most of our efforts during the 1990's attempting to develop human product applications of the underlying milk protein purification technology. Beginning in 1999, we re-focused our business strategy on the **First Defense**® product line and other products that improve the health and productivity of dairy and

beef cattle. The demand for animal protein, that must be produced efficiently while ensuring food quality and safety, increases as the human population grows. Further, our products help address the growing human health concern about using less antibiotics in food-producing animals. We aim to capitalize on the growth in sales of the **First Defense®** product line (a product that provides significant **Immediate Immunity™** to newborn dairy and beef livestock) and to revolutionize the mastitis treatment paradigm with **Re-Tain™** (formerly **Mast Out®**), a product we are developing to treat this most significant cause of economic loss to the dairy industry.

During 2000, we began the development of **Re-Tain™**, our purified Nisin treatment for subclinical mastitis in lactating dairy cows. No sales of this product can be made without prior approval of our New Animal Drug Application (NADA) by the Center for Veterinary Medicine, U.S. Food and Drug Administration (FDA). We have achieved FDA approval for four out of five of the significant regulatory submissions required for product approval, and we made the fifth and final submission during the first quarter of 2021. Regulatory achievements to date have significantly reduced the product development risks in the areas of safety and effectiveness. Our primary product development focus has now turned to completion of the manufacturing objectives required for FDA approval.

Since 2006, we have made ongoing efforts to maintain compliance with current Good Manufacturing Practice (cGMP) regulations in all of our manufacturing operations, which requires a sustained investment that further enhances the quality of all of our products and our operating efficiency. As we make process improvements, we continue to invest in personnel, equipment and facility modifications to increase the efficiency and quality of our operations.

From the first quarter of 2016 to the first quarter of 2019, we issued an aggregate of 4,037,861 shares of common stock, raising net proceeds of approximately $20.5 million in five separate transactions. In order to minimize the dilutive effects of these transactions on our existing stockholders, we chose not to issue any form of convertible or preferred securities and issued these common shares without any warrants. After refinancing our bank debt twice during 2020, we had approximately $9 million in bank debt outstanding under four different credit facilities as of December 31, 2020 compared to $8.4 million as of December 31, 2019. This new equity and debt capital has been, and is being, used to increase the production capacity for the **First Defense®** product line and complete the development of **Re-Tain™** without relying on funding from a partner or licensee, thereby keeping control over all product rights and future revenues.

During the past five years, we have funded our operations, completed a significant capital investment in our Drug Substance manufacturing facility for **Re-Tain™** and nearly completed a capital investment to increase our production capacity for the **First Defense®** product line. We have also initiated another capital investment to bring the formulation and aseptic filling capabilities for **Re-Tain™** in house in order to remove our present reliance on an outside contractor. The following table displays the changes in the balances of certain accounts over this period (in thousands, except for percentages):

	As of December 31,		$ Increase Over Five-Year Period	% Increase Over Five-Year Period
	2020	2015		
Cash, cash equivalents, short-term investments and long-term investments	$7,946	$6,524	$1,422	22%
Net working capital	$9,946	$7,056	$2,890	41%
Total assets	$40,350	$14,601	$25,749	176%
Stockholders' equity	$28,266	$10,614	$17,652	166%
Market capitalization	$42,952	$23,035	$19,917	86%
Common shares outstanding[(1)]	7,219	3,055	4,164	136%

(1) There were approximately 414,000 and 238,000 shares of common stock reserved for issuance under stock options that were outstanding as of December 31, 2020 and 2015, respectively.

Animal Health Products

The **First Defense®** product line is manufactured from hyperimmune cows' colostrum (the antibody rich milk that a cow produces immediately after giving birth) utilizing our proprietary vaccines and milk protein purification

technologies. The **First Defense**® product line provides bovine antibodies that newborn calves need but are unable to produce on their own immediately after birth. The target disease, calf scours (bovine enteritis), causes diarrhea and dehydration in newborn calves and often leads to serious sickness and even death. The **First Defense**® product line is the only USDA-licensed, orally delivered scours preventive product on the market for calves with claims against *E. coli*, coronavirus and rotavirus (three leading causes of scours). A single dose of our product provides a measured level of protection proven to reduce mortality and morbidity. Our pre-formed antibody products provide **Immediate Immunity™** during the first few critical weeks of life when calves need this protection most. Studies have shown that calves that scour are more susceptible to other diseases later in life and under-perform calves that do not contract scours. The direct, two-part mode-of-action of the **First Defense**® product line delivers specific immunoglobulins at the gut level to immediately protect against disease, while also providing additional antibodies that are absorbed into the bloodstream. These circulating antibodies function like a natural timed-release mechanism, as they are re-secreted into the gut later to provide extended protection. The **First Defense**® product line is convenient to use. A calf needs to receive only one dose of **First Defense**® within the first twelve hours after birth. The capsule format of this product is stored at room temperature and no mixing is required before it is given to the calf. The gel tube formats of this product require refrigeration in accordance with product label indications. We are the market leader (in terms of both unit volume and dollar sales) when compared to other calf-level scours preventatives but have greater market potential as we gain market share from the dam-level (pre-calving scour vaccines) competitors. The third quarter of 2020 marked the 29th anniversary of the original USDA approval of this product in 1991. During the fourth quarter of 2020, our cumulative sales of **First Defense**® since inception exceeded 26,000,000 doses. We believe that these milestones demonstrate the value of our technology and the long-term market acceptance of our product.

The **First Defense**® product line continues to benefit from wide acceptance by dairy and beef producers as an effective tool to prevent scours (diarrhea) in newborn calves. Our **Beyond Vaccination**® marketing campaign focuses on providing antibodies without vaccination. A 100% vaccine response rate is biologically impossible. The **First Defense**® product line removes the variability associated with a scour vaccine response and instead provides a measured level of pre-formed antibodies, protecting each calf with an equal level of scours protection. There is a strong link between how we sell our product and the challenges we face in producing it. We know better than most how variable a cow's response is to any vaccine. We see this in every batch of **First Defense**® that we produce. The value in **First Defense**® is that we adjust for this variability in antibody content, as needed, so the newborn is given a steady, equal level of protection with each dose. This technology removes a producer's reliance on variable vaccine responses to generate passive antibody protection and instead protects every calf equally with a measured dose of **Immediate Immunity™** against the most common scour pathogens. Plus, an effectively treated calf is much less likely to require expensive antibiotic treatments or build antibiotic resistance. We are the only manufacturer within the scour prevention space offering polyclonal multi-pathogen antibodies. The market is learning that the best preventative for scours may not be a vaccine. We are educating the market about the health benefits of a measured dose of pre-formed antibodies.

The product line extension, **Tri-Shield First Defense®**, is the first calf-level, passive antibody product on the market with USDA-approved disease claims providing **Immediate Immunity™** against each of the three leading causes of calf scours (*E. coli*, coronavirus and rotavirus). This new product achieved USDA approval during the fourth quarter of 2017 and was listed with the Organic Materials Research Institute (OMRI) during the first quarter of 2019, which means it can be used on organic farms. **Tri-Shield®** combines the *E. coli* and coronavirus antibodies contained in our bivalent product with a measured level of rotavirus antibody in a single-dose gel tube delivery format. This unique breadth of claims further differentiates our product from calf-level competitive products on the market that contain only one or two of these label claims. The unique virus like particle (VLP) technology that is used in our production process increases rotavirus titers in colostrum to a level much greater than traditional vaccine technology can. Because it is possible that all farms may not have (or perceive to have) a rotavirus problem, we are continuing to sell the bivalent formats of the **First Defense®** product line as options for customers.

Historically, the most common tool to help combat scours has been to vaccinate the mother cow (dam) with a scours vaccine and deliver the antibodies that she produces to the newborn. It is generally believed that only 80% of animals respond to a vaccine, which could leave about 20% of calves unprotected. We believe that the variability in a cow's immune response to vaccines creates a sales opportunity for our product. Additionally, our research suggests that treatment protocols for dam-level scours vaccine programs are not always followed, leaving even more calves compromised. We are competing effectively against these dam-level vaccine products. Our marketing campaign,

Beyond Vaccination®, emphasizes that by delivering **Immediate Immunity™** directly to the calf via the **First Defense®** product line, producers can reduce stress-causing injections to the cow. Reliance on a dam-level scours vaccine requires that money be spent before it is known whether the cow is carrying a viable, valued calf. With the **First Defense®** product line, that investment can be targeted to the calves that are most critical to the operation. This, in turn, can free up space in the cow's vaccination schedule to improve her immune response to vaccines that are critical to her health.

We believe that the long-term growth in sales of the **First Defense®** product line may reflect, at least in part, the success of our strategic decision to invest in additional sales and marketing efforts to help us introduce the expanding **First Defense®** product line to new customers. Our communications campaign continues to emphasize how the unique ability of the **First Defense®** product line to provide **Immediate Immunity™** generates a dependable and competitive return on investment for dairy and beef producers. Preventing newborn calves from becoming sick helps them to reach their genetic potential and reduces the need to use treatment antibiotics later in life.

First Defense Technology® is a unique whey protein concentrate that is processed utilizing our proprietary colostrum (first milk) protein purification methods, for the nutritional and feed supplement markets without the claims of our USDA-licensed product. During 2012, we initiated a limited launch of a gel tube delivery format of our **First Defense Technology®** in a gel solution. We achieved USDA claims for this product format during the fourth quarter of 2018 and Canadian approval during the first quarter of 2019, and it is now being sold as **Dual-Force First Defense®**. We are selling the same concentrated whey proteins in a bulk powder format (no capsule), which is delivered with a scoop and mixed with colostrum for feeding to calves. We are working to achieve USDA claims for this product format during 2021. During 2011, Milk Products, LLC of Chilton, Wisconsin launched commercial sales of their product, Ultra Start® 150 Plus and certain similar private label products, which are colostrum replacers with **First Defense Technology® Inside**.

During 2001, we began to offer our own, internally developed **California Mastitis Test (CMT)**. **CMT** is most often used as a quick on-farm diagnostic to determine which quarter of the udder is mastitic. This test can be performed at cow-side for early detection of mastitis. **CMT** products are also made by other manufacturers and are readily available to the dairy producer. In connection with our acquisition of certain gel formulation technologies during the first quarter of 2016, we acquired private label manufacturing rights covering a feed supplement product sold by Genex Cooperative, Inc. of Shawano, WI.

Sales and Markets

Our sales and marketing team consists of one vice president, seven regional managers (including one open position) and one director of marketing and customer service. The **First Defense®** product line and **CMT** are sold primarily through major animal health distributors who, in turn, sell to veterinary clinics, fleet stores and direct to farms. Sales of the **First Defense®** product line are normally seasonal, with higher sales expected during the first quarter, largely driven by the beef calving season, which runs primarily from January to April, unlike the dairy industry in which operations generally calve year round. Warm and dry weather reduces the producer's perception of the need for a disease preventative product like the **First Defense®** product line. However, heat stress on calves caused by extremely hot summer weather can increase the incidence of scours, just as harsher winter weather benefits our sales. Other competition for resources that dairy producers allocate to their calf enterprises has been increased by the many new products (principally feed supplements) that have been introduced to the calf market. Despite the market volatility affecting both milk prices and feed costs, we continue to increase our sales.

We estimate that the total U.S. market for scours preventative products (including sales of our product) that are given to newborn calves (the calf-level market) is approximately $23.4 million per year. With the additional claim for our new product (**Tri-Shield First Defense®**) against rotavirus, we are now competing against the dam-level vaccine products that are given to the mother cow to increase the antibody level against specific scours-causing pathogens in the colostrum that she produces for her newborn. We estimate that the dam-level product category covers approximately twice as many calves as the calf-level product segment reaches. We estimate that the total domestic addressable market (both calf and dam levels) is approximately $68.1 million per year.

The majority of our international sales are to Canada. We price our products in U.S. dollars. To the extent that the value of the dollar declines with respect to any other currency, our competitive position may be enhanced. Conversely, an increase in the value of the dollar in any country in which we sell products may have the effect of

increasing the local price of our products, thereby leading to a potential reduction in demand. Generally, our international sales have been generated through relationships with in-country distributors that have knowledge of the local regulatory and marketing requirements. We are initiating our plan to expand the number of countries to which our **First Defense**® product line is approved for export. Generally, it is our intent to be the holder of these product registrations for each country rather than rely on distribution partners to gain and hold these registrations. This is a long regulatory process but allows us to maximize the use of our product label claims. We continue our efforts to grow sales of the **First Defense**® product line in North America, where there are approximately 41 million dairy and beef cows in the United States and 4.6 million dairy and beef cows in Canada. We believe that significant market opportunities exist in other international territories. The statistics above are provided by an industry compilation of USDA data for 2021. Industry practices, economic conditions, cause of disease, distribution channels and regulatory requirements may differ in these international markets from what we experience in North America, potentially making it more difficult or costly for us to generate and sustain sales volumes at profitable margins in these markets.

We introduced **First Defense**® into South Korea in 2005 through Medexx Co., Ltd of Gyeonggi-do, Korea and its equivalent into Japan in 2007 through NYS Co., Ltd of Iwate, Japan. The business in Japan is currently not active, but we are working to resume sales in this territory. We entered into distribution contracts covering certain Middle Eastern countries with Triplest for Drugs and Trade of Madaba, Jordan during the first quarter of 2017 (no sales have yet been achieved under this contract) and covering Iran with Senikco, LLC of Laguna Niguel, CA during the fourth quarter of 2016 (sales have been initiated under this contract).

With **Re-Tain™**, we are working to expand our product offerings to include an intramammary treatment for subclinical mastitis for the mother cow during lactation. Nisin (the active ingredient in **Re-Tain™**) is a bacteriocin that is not used in human medicines and could alleviate some of the social concerns that the widespread use of antibiotics encourages the growth of antibiotic-resistant bacteria (“superbugs”). Mastitis (inflammation of the mammary gland) is estimated to cost the U.S. dairy industry approximately $2 billion in economic harm per year, which makes it the most costly and common disease affecting the dairy industry. The disease diminishes the saleable quantity and overall value of milk, in addition to causing other herd health and productivity losses. While the benefit of treating clinical mastitis is widely known, subclinical mastitis (those cases where cows have infected udders, but still produce saleable milk) is associated with its own significant economic losses and is recognized as a substantial contributor to clinical mastitis cases. There is a growing awareness of the cascade of adverse events and conditions associated with subclinical mastitis for both the dairy producer and the milk processor, including reduced or foregone milk quality premiums, lower milk production (some have estimated approximately 1,500 pounds of lost milk, or about $270 at $18.00 per hundredweight, per infected cow), shorter shelf life for fluid milk, lower yields and less flavor for cheese, higher rates of clinical mastitis, lower conception rates, increased abortions and increased cull rates. Some industry experts have estimated that subclinical mastitis costs the U.S. dairy industry approximately $1 billion per year.

We believe that **Re-Tain™** could revolutionize the way that mastitis is treated by making earlier treatment of subclinically infected cows (while these cows are still producing saleable milk) economically feasible by not requiring a milk discard during, or for a period of time after, treatment, which would be a significant competitive advantage for our product. No other FDA-approved mastitis treatment product on the market can offer this value proposition. It is generally current practice to treat mastitis only when the disease has progressed to the clinical stage where the milk from an infected cow cannot be sold. Because the milk from cows treated with traditional antibiotics must be discarded, most dairy producers simply do not treat subclinically infected cows. The ability to treat such cases without a milk discard could revolutionize the way mastitis is managed in a herd. It is common practice to move sick cows from their regular herd group to a sick cow group for treatment and the related milk discard. This movement causes stress on the cow and a reduction in milk production. Cows treated with our product would not have to be moved, allowing this costly drop in production to be avoided. Our product likely will be priced at a premium to the traditional antibiotic products currently on the market, which are all sold subject to a milk discard requirement. Common milk discard periods cover the duration of treatment and extend from 1.5 to 3 days after last treatment, depending on the antibiotic. On average, a cow produces approximately 60 to 80 pounds of milk per day. While milk prices vary significantly, at an average value of $18.00 per 100 pounds, a cow produces approximately $10.80 to $14.40 worth of milk per day. These estimated figures would result in milk discard costs ranging from approximately $37.80 (for 3.5 days of milk at 60 pounds per day) to $158.40 (for 11 days of milk at 80 pounds per day) per treated animal. We estimate that the approximate cost to the U.S. dairy industry of this discarded milk may be around $300 million per year. These high milk discard costs associated with traditional antibiotic treatments lead

producers to only treat mastitis after clinical signs develop. The **Re-Tain™** label will be for subclinical mastitis (not clinical). Without a milk discard cost, we expect producers to be more motivated to identify and treat cows at the subclinical stage. We believe that the product's value proposition demonstrates a return on investment to the dairy producer and the milk processor that will justify a premium over other mastitis treatments on the market today.

The USDA's National Animal Health Monitoring System through its Dairy 2014 study suggests that 21% of all dairy cows are treated with a mastitis drug, of which approximately 51% are treated with third generation cephalosporins. Many fear that the possible overuse of antibiotics in livestock undermines the effectiveness of drugs to combat human illnesses and contributes to a rising number of life-threatening human infections from antibiotic-resistant bacteria, commonly known as "superbugs". The FDA is committed to addressing this public health risk. Citing concerns about untreatable, life-threatening infections in humans, new FDA and European regulations are aimed at restricting the use of antibiotics (including cephalosporins) in food animals and at improving milk quality. Regulators have recently increased their monitoring of antibiotic residues in milk and meat. During the first quarter of 2012, the USDA reduced the allowable level of somatic cell counts (SCC) in milk from 750,000 (cells per milliliter) to 400,000 at the individual farm level (not a blended calculation of comingled milk) in order to qualify for an EU health certification for export.

The FDA's Veterinary Feed Directive (VFD) became effective January 1, 2017, restricting the use of medically important antibiotics for performance purposes and requiring more oversight of antibiotic usage in food producing animals by a veterinarian, and more changes and restrictions relating to antibiotic usage appear to be likely. Several major food processors and retailers have implemented policies addressing this growing public health concern. By reducing the risk of antibiotic residues and slowing the development of antibiotic-resistant organisms, we can improve food quality and preserve medically important antibiotics for human disease treatment. This would not be a concern for **Re-Tain™** because Nisin is not used for human health. This current environment is favorable to the introduction of our new product as an alternative to traditional antibiotics such as penicillin and cephalosporins. We believe that this changing environment of new regulations and public opinion supports the value of our ongoing development and commercialization efforts for **Re-Tain™**. Additionally, we believe that the use of our **First Defense®** product line is consistent with this trend of reducing the use of antibiotics because the prevention of calf scours early in life with our purified colostrum antibodies can reduce the need for treatment antibiotics later in a calf's life.

It is difficult to estimate the potential size of the market for the treatment of subclinical mastitis because presently this disease is largely left untreated. We believe that approximately 20-30% of the U.S. dairy herd is affected by subclinical mastitis caused by Gram-positive organisms falling within the claim spectrum of our product. This compares to approximately 2% of the U.S. herd that is thought to be infected with clinical mastitis, where approximately $60 million per year is spent on drug treatments. Finding candidate cows will require farms to obtain monthly individual cow somatic cell count (SCC) data through participation in organizations such as the National Dairy Herd Information Association (DHIA) or by installing monitors to indicate high SCC cows or a potential health event. Only about 50% of cows are on DHIA test today. Similar market opportunities are likely to exist outside the U.S. We believe the use of **Re-Tain™** could be expanded with additional data to support treatment late in lactation and possibly for clinical stage mastitis. We also believe there may be a market for use in small ruminates, where the majority of mastitis cases are caused by strep-like organisms aligned with our effectiveness data. Given what we believe to be reasonable assumptions, we estimate that the U.S. market potential for first year sales of our new product could be approximately $5.8 million and could grow to approximately $36.1 million during the fifth year after market launch. However, due to our limited sales and marketing resources and the significant challenges inherent in a small company inducing large numbers of producers to quickly embrace a new technology, we presently expect actual **Re-Tain™** sales to be substantially below those levels, at least in the early stages of the **Re-Tain™** launch. The amount of sales that we can capture from this estimated market potential and the timing of when this can be achieved is very difficult to know, and the actual size of the market for our new product may differ materially from our estimates (up or down). We expect the Drug Substance production facility that we constructed for approximately $20.8 million to have initial annual production capacity sufficient to meet at least $10 million in sales of **Re-Tain™** at current production yields. This production capacity estimate does not yet reflect any inventory build strategies in advance of product approval or ongoing yield improvement initiatives. Our new facility is designed to have enough room to add a second fermentation and recovery portion of the production line to be purchased and installed at the cost of approximately $7 million to effectively double production output. We would consider making this investment only after commercial acceptance of the product is demonstrated. That being said,

we are presently planning to use the space originally intended for the second Drug Substance fermentation and recovery production line for the installation of a Drug Product formulation and aseptic filling module. Thus, expansion of the estimated annual capacity of the Drug Substance facility beyond approximately $10 million (without factoring in potential yield improvements) would now require relocation of the Drug Product formulation and aseptic filling module to another facility, or the acquisition and equipping of other Drug Substance production facilities at substantial additional cost or alternative manufacturing strategies.

With a measured approach to expanding our customer-facing staff, it is our objective to increase our current annual level of product sales of just over $15 million to approximately $23 million through both continued growth in sales of the **First Defense**® product line and a successful launch of **Re-Tain™** as soon as possible. As market penetration for both new products is achieved and additional resources are dedicated to production, sales, marketing and technical services, our longer-term goal is to exceed the $30 million level of annual product sales as soon as possible during the five-year period after the market launch of **Re-Tain™**.

Product Development

The majority of our product development spending has been focused on the development of **Re-Tain™**, our purified Nisin treatment for subclinical mastitis in lactating cows. During the 21-year period that began on January 1, 2000 and ended on December 31, 2020, we invested an aggregate of approximately $19.8 million (excluding depreciation and the capital cost of our Drug Substance production facility) in the development of this product. This estimated allocation reflects only direct expenditures and includes no allocation of product development or administrative overhead expenses. Approximately $2.9 million of this investment was offset by related product licensing revenues and grant income, most of which was earned from 2001 to 2007.

During 2000, we acquired an exclusive license from Nutrition 21, Inc. (formerly Applied Microbiology Inc. or AMBI) to develop and market Nisin-based products for animal health applications, which allowed us to initiate the development of **Re-Tain™**. In 2004, we paid Nutrition 21 approximately $965,000 to buy out this royalty and milestone-based license to Nisin, thereby acquiring control of the animal health applications of Nisin. Nisin is a well characterized substance, having been used in food preservation applications for over 50 years. Food-grade Nisin, however, cannot be used in pharmaceutical applications because of its low purity. Our Nisin technology includes patented processing and purification methods to achieve pharmaceutical-grade purity.

During 2004, we entered into a product development and marketing agreement with Zoetis (formerly Pfizer Animal Health, a division of Pfizer, Inc.) covering this product. That company elected to terminate the agreement in 2007. We believe that this decision was not based on any unanticipated efficacy or regulatory issues. Rather, we believe the decision was primarily driven by a marketing concern relating to their fear that the milk from treated cows could interfere with the manufacture of certain cultured dairy products. Due to the zero milk discard feature, there is a risk that Nisin from the milk of treated cows could interfere with the manufacture of certain (but not all) commercial cultured dairy products, such as some kinds of cheese and yogurt, if a process tank contains a high enough percentage of milk from treated cows. The impact of this potential interference ranges from a delay in the manufacturing process (which does happen at times for other reasons) to the less likely stopping of a cheese starter culture. Milk from cows that have been treated with our product that is sold exclusively for fluid milk products presents no such risk. We worked with scientists and mastitis experts to conduct a formal risk assessment to quantify the impact that milk from treated cows may have on cultured dairy products. This study concluded that the dilution of milk from treated cows through comingling with milk from untreated cows during normal milk hauling and storage practices reduces the risk of interference with commercial dairy cultures to a negligible level when the product is used in accordance with the product label. Further, we believe that such a premium-priced product will be used selectively, which reduces the risk of cheese interference and is consistent with modern “precision dairying” practices that discourage the indiscriminate use of drug treatments.

Subclinical mastitis, and the study required to achieve an effectiveness claim for it, is defined under the FDA/Center for Veterinary Medicine Guidance #49: Target Animal Safety and Drug Effectiveness Studies for Anti-Microbial Bovine Mastitis Products (Lactating and Non-Lactating Cow Products). Trial eligibility requires both pretreatment samples to be positive for the mastitis pathogen (except for *Staphylococcus aureus* and *Streptococcus agalactiae*, where a single pretreatment sample qualifies a cow for enrollment). For all pathogens, both samples taken between 14 and 28 days post treatment (and at least 5 days apart) must be negative to be judged a cure. These conservative criteria generally result in enrolling cows with chronic subclinical disease, which rarely self-resolves.

Milk from cows infected with subclinical mastitis has greater somatic cell counts (SCC), and producers may be paid less for this lower quality milk. Cows with subclinical mastitis infections are known to produce less milk, and cows that maintain subclinical mastitis across the dry period have been shown to produce significantly less milk. The failure to treat subclinical mastitis may result in chronic infections that are unlikely to respond to antibiotic therapy. Finally, cows with subclinical mastitis maintain a reservoir of infection within the herd and increase exposure of healthy cows to contagious pathogens.

Our second most important product development initiatives (in terms of dollars invested and, we believe, potential market impact) have been focused on other improvements, extensions or additions to our **First Defense®** product line. During the second quarter of 2009 we entered into a perpetual, exclusive license with the Baylor College of Medicine covering the underlying rotavirus vaccine technology used to generate the specific antibodies for use with animals. We achieved product license approval and initiated market launch of this product, **Tri-Shield First Defense®**, during the fourth quarter of 2017. During the third quarter of 2018, we obtained approval from the Canadian Food Inspection Agency to sell **Tri-Shield®** in Canada. We initiated sales in Canada through our in-country distributor during the fourth quarter of 2019. We achieved USDA approval of our bivalent gel tube formulation (formerly marketed as **First Defense Technology®**) during the fourth quarter of 2018 and have re-branded this product format as **Dual-Force First Defense®**. We are currently working to establish USDA claims for our bivalent bulk powder formulation of **First Defense Technology®**.

We are also working to expand our product development pipeline of bacteriocins that can be used as alternatives to traditional antibiotics through expansions of our Nisin technology and yield improvements. Subject to the availability of resources, we intend to begin new development projects that are aligned with our core competencies and market focus. We also remain interested in acquiring, on suitable terms, other new products and technologies that fit with our sales focus on the dairy and beef industries.

Competition

Our competition in the animal health market includes other biotechnology companies and major animal health companies. Most, if not all, of these competitors have substantially greater financial, marketing, manufacturing and human resources and more extensive product development capabilities than we do.

We would consider any company that sells an antibiotic to treat mastitis, such as Boehringer Ingelheim, Merck Animal Health and Zoetis, to be among the potential competitors with respect to **Re-Tain™**. We expect the FDA to grant a period of five years of market exclusivity for our product (meaning the FDA would not grant approval to a second NADA with the same active drug for a period of five years after the first NADA approval is granted) under Section 512(c)(2)F of the Federal Food, Drug, and Cosmetic Act. The Nisin A to which we have exclusive rights for animal health applications is produced from our high-yielding, proprietary *L. lactis* strain and purified to a high level, providing us with a level of protection over a competitor that might try to develop a similar product.

There are several other products on the market (some with claims and some without) that are delivered to newborn calves to prevent scours. We believe that the **First Defense®** product line offers two significant competitive advantages. First, only the **First Defense®** product line provides protection against *E. coli*, coronavirus and rotavirus, three of the leading causes of calf scours. Second, being derived from colostrum, our product offers **Immediate Immunity™** through antibodies that both function at the gut level and are absorbed into the blood stream for future protection. All formats of our product can be administered immediately after birth and are not negatively affected by maternal colostrum.

Zoetis sells a product that competes directly with the **First Defense®** product line in preventing scours via oral delivery to newborn calves. Their product (Calf-Guard®) is a modified-live virus vaccine. Newborn calves respond poorly to vaccines and the immune system must be given time to develop a response to vaccines. Both our product and Calf-Guard® carry claims against coronavirus and rotavirus infections, but this competitive product does not carry a claim against *E. coli* infections like our product does. It is common practice to delay colostrum feeding when dosing a calf with Calf-Guard® so that the antibodies in the colostrum do not inactivate this vaccine product. There is no nutritional or health benefit to withholding milk from newborn calves. In contrast, we encourage the feeding of four quarts of high quality colostrum immediately after birth when dosing a calf with our product, which is standard practice for good calf health. Because the antibodies in our product would likely work to inactivate a modified-live virus vaccine, rendering it useless or less useful, our product label historically included a precaution that **First Defense®** should not be used within five days of such a vaccine. During the first quarter of 2015, the USDA granted

us permission to remove this precaution from our label, and we have done so. We believe that this precaution should be required on the Calf-Guard® label to prevent inactivation of that product by **First Defense®** antibodies or by colostrum. Our product is priced at a premium to Calf-Guard®.

During the fourth quarter of 2016, Merck launched a new competitive product into this market space. This product (BOVILIS® Coronavirus) is a modified-live virus intranasal vaccine that carries a claim against coronavirus only.

Around the end of 2019, Elanco Animal Health gave notice to the market that it had discontinued the manufacture of its competitive products, Bovine Ecolizer® and Bovine Ecolizer + C20, and subsequently exited the market during the first quarter of 2021. This product was the smallest of our three significant calf-level competitors.

When compared to the other USDA-approved calf-level scours preventatives, we lead in both sales dollars and calves treated within the U.S. market. This product category is comprised of the four primary brands discussed above that are given either orally or intranasal to newborn dairy and beef calves immediately after birth. With the new rotavirus claim for our product (**Tri-Shield First Defense®**), we are now also competing against dam-level vaccine products that are given to the mother cow to increase the antibody level against scours-causing pathogens in the colostrum that she produces for her newborn. Those products are sold by Elanco (Scour Bos™), Merck (Guardian®) and Zoetis (ScourGuard®). Despite the best-managed dam vaccine program, colostrum quality is naturally variable and newborn calves do not always get the antibodies they need from maternal colostrum. We believe that the measured dose of antibodies in our product provides more consistent protection than such vaccine products.

We may not be aware of competition that we face, or may face in the future, from other companies. Our competitive position will be highly influenced by our ability to attract and retain key scientific, manufacturing, managerial and sales and marketing personnel, to develop proprietary technologies and products. We need to obtain USDA, FDA or foreign approvals for new products to effectively promote and market our products. We must have available properly licensed, efficient and effective raw material and finished product manufacturing resources to continue to profitably sell our current products. We currently compete on the basis of product performance, price and distribution capability. We continue to monitor our network of independent distributors to maintain our competitive position.

Intellectual Property

We own a broad collection of intellectual property rights relating to our research, products and processes. This includes: patents, copyrights, trademarks, trade dress, trade secrets, know-how and other intellectual property rights in the United States and other countries. We believe the ownership of our intellectual property rights is an important factor in our business and that our success depends in part on such ownership. We also rely heavily on the innovative skills, technical competence and marketing abilities of our personnel. The Nisin A that is produced from our proprietary strain of *L. lactis* is an essential component of our intellectual property covering **Re-Tain™**.

We own: (a) U.S. Patent No. 6,794,181 entitled “Method of Purifying Lantibiotics”, which covers a manufacturing process for preparing pharmaceutical-grade Nisin, which was issued in 2004; and (b) U.S. Patent No. 10,023,617 entitled “Methods and Systems of Producing Pharmaceutical Grade Lantibiotics”, which covers key, novel and proprietary aspects of our manufacturing process for preparing pharmaceutical-grade Nisin, and was issued during the third quarter of 2018. In the future, we may file additional patent applications for certain products under development. There can be no assurance that patents will be issued with respect to any pending or future applications. In some cases, we have chosen (and may choose in the future) not to seek patent protection for certain products or processes. In those instances, we have sought (and may seek in the future) to maintain the confidentiality of any relevant intellectual property and other proprietary rights through operational measures and contractual agreements.

We own numerous trademarks and trade dress that are very important to our business, and have several trademark and trade dress applications and registrations in the United States, Canada, Iran and Turkey. We own the following U.S. trademark registrations: **IMMUCELL**, **FIRST DEFENSE**, **FD FIRST DEFENSE (& Design), FIRST DEFENSE TECHNOLOGY**, **TRI-SHIELD FIRST DEFENSE, TRI-SHIELD FIRST DEFENSE (& Design), YOUR CALF CREW, BEYOND VACCINATION, BEYOND VACCINATION (& Design), CALF HERO, DUAL-FORCE, TRI-SHIELD and MAST OUT.** We also own U.S. registrations claiming rights in the color blue for our blue gel and blue bolus **FIRST DEFENSE** products**.** We own a pending U.S. trademark application

for the **RE-TAIN** trademark. The United States Patent and Trademark Office refused registration of our **IMMEDIATE IMMUNITY** trademark, which we use extensively in connection with marketing of all of our products, on the grounds that the mark is generic. Rather than appeal this finding, we are continuing to build our common law rights in the brand. The FDA issued a determination that the name, **MAST OUT**, which we had intended to use for our purified Nisin product, is overly promotional. Rather than continuing an appeal of this decision, we selected a new product name, **RE-TAIN**, which was approved by the FDA during the first quarter of 2019.

Government Regulation

We believe that we are in compliance with current regulatory requirements relating to our business and products. The manufacture and sale of animal health biologicals within the United States is generally regulated by the USDA. We have received USDA and Canadian Food Inspection Agency approval for the bolus format of **First Defense®** and for the gel tube formats of **Tri-Shield First Defense®** and **Dual-Force First Defense®**. **Re-Tain™** is regulated by the FDA, which regulates veterinary drugs. Regulations in the European Union will likely require that our product be sold subject to a milk discard requirement in that territory, although the duration of the milk discard requirement may be shorter than the discard requirement applicable to competitive antibiotic products in that market. Comparable agencies exist in foreign countries, and foreign sales of our products will be subject to regulation by such agencies. Many countries have laws regulating the production, sale, distribution or use of biological products, and we may have to obtain approvals from regulatory authorities in countries in which we propose to sell our products. Depending upon the product and its applications, obtaining regulatory approvals may be a relatively brief and inexpensive procedure or it may involve extensive clinical tests, incurring significant expenses and an approval process of several years' duration. We generally rely on in-country experts to assist us with or to perform international regulatory applications.

Employees

We currently employ 61 employees (including 5 part-time employees) in comparison to 54 employees (including 3 part-time employees) approximately a year ago. Approximately 35.9 full-time equivalent employees are engaged in manufacturing operations, 9.4 full-time equivalent employees in sales and marketing, 7.6 full-time equivalent employees in product development activities (primarily supporting facility maintenance and operation, regulatory filings and commercial scale-up for **Re-Tain™**) and 5.6 full-time equivalent employees in finance and administration. As needed, we augment our staff with contracted temporary employees. All of our employees are required to execute non-disclosure and invention assignment agreements (and some are required to execute non-compete agreements) intended to protect our rights in our proprietary products. We are not a party to any collective bargaining agreement and consider our employee relations to be excellent.

Public Information

As a reporting company, we file quarterly and annual reports with the Securities and Exchange Commission (SEC) on Form 10-Q and Form 10-K. We also file current reports on Form 8-K, whenever events warrant or require such a filing. The public may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an internet site that contains reports, proxy and information statements and other information about us that we file electronically with the SEC at *http://www.sec.gov*. Our internet address is *http://www.immucell.com*.

ITEM 1A — RISK FACTORS

Financial Risks

Gross margin on product sales: One of our goals is to achieve a gross margin (before related depreciation expenses) as a percentage of total sales close to 50% after the initial launch of new products. Depreciation expense will be a larger component of costs of goods sold for **Re-Tain™** than it is for the **First Defense®** product line. Gross margins generally improve over time, but this anticipated improvement may not be realized. Many factors discussed in this report impact our costs of goods sold. There is a risk that we are not able to achieve our gross margin goals, which would adversely affect our operating results and could impact our future operating plans.

Exposure to interest rates and debt service obligations: Rising interest rates could negatively affect the operating costs of dairy and beef producers and thus put further financial pressure on an already stressed business sector, which could indirectly affect our business. We removed the direct aspect of this particular exposure to our business by refinancing our bank debt to fixed rate notes at 3.5% per annum during the first quarter of 2020. The additional debt we incurred to fund the development of **Re-Tain™** has significantly increased our debt service costs. We are obligated to make principal and interest payments aggregating approximately $1.1 million, $1.1 million and $1.2 million during the years ending December 31, 2021, 2022 and 2023, respectively. See Note 10 to the accompanying audited financial statements for more information.

Debt covenants: Our bank debt is subject to certain financial covenants. Prior to the bank debt refinancing that we completed during the fourth quarter of 2020, our bank held $1.4 million in escrow (non-current asset). By using $624,000 of the proceeds from our bank debt refinancing during the fourth quarter of 2020 to prepay a portion of our mortgage loan, we reduced the then outstanding balance of the mortgage loan to 80% of the most recent appraisal value, which allowed the bank to release these funds from escrow. We are required to meet a minimum debt service coverage ratio set by the bank of 1.35. This debt service coverage ratio was 2.03 and 1.57 for the years ended December 31, 2020 and 2019, respectively. Based on our projected financial performance, we may not satisfy this annual requirement for the year ending December 31, 2021. There is a risk that we may not be able to reach an agreement with our bank to waive this covenant requirement during the first quarter of 2022.

Projection of net income (loss): Generally speaking, our financial performance can differ significantly from management projections, due to numerous factors that are difficult to predict or that are beyond our control. Weaker than expected sales of the **First Defense®** product line could lead to less profits or deeper operating losses. The timing of FDA approval of **Re-Tain™** and the initiation of commercial sales of that product will have a material impact on our net (loss) income during 2021 and 2022. Additionally, this complexity and uncertainty is magnified by the risks relating to and arising out of the duration, extent and nature of adverse effects from the COVID-19 pandemic.

*Risks associated with our funding strategy for **Re-Tain™**:* Failure to maintain adequate cash and liquidity to support the commercialization of **Re-Tain™** is a risk to our business. Achieving FDA approval of our pharmaceutical-grade Nisin produced at commercial-scale is the most critical action remaining in front of us on our path to U.S. regulatory approval of **Re-Tain™**. Having completed the construction and equipping of the Drug Substance production facility described elsewhere in this report at a cost of approximately $20.8 million, we will continue to incur product development expenses to operate and maintain this facility. Absent sufficient sales of **Re-Tain™** at a profitable gross margin, we would be required to fund all debt service costs from sales of the **First Defense®** product line, which would reduce, and could eliminate, our expected profitability going forward and significantly reduce our cash flows.

Uncertainty of market size and product sales estimates: Estimating the size of the total addressable market and future sales growth potential for our **First Defense®** product line is based on our experience and understanding of market dynamics but is inherently subjective. Estimating the size of the market for any new product, such as **Re-Tain™**, involves more uncertainties than do projections for established products. We do not know whether, or to what extent, our products will achieve, maintain or increase market acceptance and profitability. Some of the uncertainties surrounding **Re-Tain™** include the product's effectiveness against prevalent pathogens, market acceptance, the effect of a premium selling price on market penetration, cost of manufacture and competition from new and existing products sold by substantially larger competitors with greater market reach and promotional resources. Since **Re-Tain™** is a novel approach to treating mastitis, there are many uncertainties with regards to how quickly and to what extent we can develop the subclinical mastitis treatment market. Producers' current

practice generally is to treat only clinical mastitis, which has the visual indicator of abnormal milk. We will need to change that practice and increase awareness of the importance of treating subclinical disease. This will require the producers' ability and willingness to diagnose without visual indicators. There is a risk that dairy producers and processors will not accept this new technology because of the risk that it may negatively effect cheese making if present in a high enough concentration in any cheese batch that utilizes a starter culture that is susceptible to Nisin. Reducing this risk somewhat is our belief that bacteriocin technology (over traditional antibiotics) is expected to be viewed positively.

Net deferred tax assets: The realizability of our net deferred tax assets is a subjective estimate that is contingent upon many variables. During the second quarter of 2018, we recorded a full valuation allowance against our net deferred tax assets that significantly increased our net loss in comparison to other periods. This non-cash expense could be reversed, and this valuation allowance could be reduced or eliminated, if warranted by our future profitability and projected profitability in the future. We will continue to assess the need for the valuation allowance at each quarter.

Product Risks

Product risks generally: The sale of our products is subject to production, financial, efficacy, regulatory, competitive and other market risks. Elevated standards to achieve and maintain regulatory compliance required to sell our products continue to evolve. Failure to achieve acceptable biological yields from our production processes can materially increase our costs of goods sold and reduce our production output, leading to an order backlog that could adversely affect our customer relationships and operating results. There is no assurance that we will continue to achieve market acceptance of the **First Defense®** product line at a profitable price level or that we can continue to manufacture our products at a low enough cost to result in a sufficient gross margin to justify their continued manufacture and sale. Similar concerns exist with **Re-Tain™** as we bring that product to market, which could be heightened by the additional uncertainties associated with introducing a new product requiring a shift in customer behavior.

*Reliance on sales of the **First Defense®** product line:* We are reliant on the market acceptance of the **First Defense®** product line to generate product sales and fund our operations. Our business would not have been profitable during the nine consecutive years in the period ended December 31, 2007, during the years ended December 31, 2012, 2013, 2015 and 2016, during the nine-month period ended September 30, 2017 or during the three-month period ended March 31, 2019, without the gross margin that we earned on sales of the **First Defense®** product line.

Concentration of sales: Sales of the **First Defense®** product line aggregated 98% and 97% of our total product sales during the years ended December 31, 2020 and 2019, respectively. Our primary customers for the majority of our product sales (89% during both of the years ended December 31, 2020 and 2019) are in the U.S. dairy and beef industries. Product sales to international customers, who are also in the dairy and beef industries, aggregated 11% and 10% of our total product sales during the years ended December 31, 2020 and 2019, respectively. The concentration of our sales from one product into one market is a risk to our business. The animal health distribution segment has been aggressively consolidating over the last few years with larger distributors acquiring smaller distributors. A large portion of our product sales (71% and 69% during the years ended December 31, 2020 and 2019, respectively) was made to two large distributors. A large portion of our trade accounts receivable (75% and 76% as of December 31, 2020 and 2019, respectively) was due from these two distributors. We have a good history with these distributors, but the concentration of sales and accounts receivable with a small number of customers does present a risk to us, including risks related to such customers experiencing financial difficulties or altering the basis on which they do business with us in a manner unfavorable to us.

Production capacity constraints: During the second quarter of 2021, we expect to complete an investment of approximately $3.5 million to increase our production capacity (in terms of annual sales dollars) for the **First Defense®** product line from approximately $16.5 million to approximately $23 million based on current selling prices and estimated production yields. While this capacity expansion investment is currently proceeding on budget, there is a risk of cost overruns in any future production expansions that we may undertake, and a risk that we will not be able to achieve our production capacity growth objectives on a timely basis, resulting in a continuing or increasing short fall in supply to the market. The inability to meet market demand for our products is a risk to our business. The large backlog of orders aggregating approximately $1.8 million as of December 31, 2020, as well as any ongoing order

backlog, presents a risk that we could lose customers during this period that are not easily regained thereafter, when our production capacity is expected to meet or exceed sales demand. Our plan to continue to expand the **First Defense®** product line requires ongoing review of equipment capacity and utilization across the manufacturing value stream at the 56 Evergreen Drive facility and our leased facility at 175 Industrial Way, as well as assessment of functional obsolescence and reliability of equipment. This review and assessment could identify a need to fund unexpected equipment maintenance or replacement costs.

Product liability: The manufacture and sale of our products entails a risk of product liability. Our exposure to product liability is mitigated to some extent by the fact that our products are directed towards the animal health market. We have maintained product liability insurance in an amount which we believe is reasonable in relation to our potential exposure in this area. We have no history of claims of this nature being made.

Regulatory Risks

*Regulatory requirements for the **First Defense®** product line:* **First Defense®** is sold in the United States subject to a product license from the Center for Veterinary Biologics, USDA, which was first obtained in 1991, with subsequent approvals of line extensions in 2017 and 2018. As a result, our operations are subject to periodic inspection by the USDA. The potency of serial lots is directly traceable to the original serial used to obtain the product performance claims (the Reference Standard). Due to the unique nature of the label claims, host animal re-testing is not required as long as periodic laboratory analyses continue to support the stability of stored Reference Standard. To date, these analyses have demonstrated strong stability. However, if the USDA were not to approve requalification of the Reference Standard, additional clinical studies could be required to meet regulatory requirements and allow for continued sales of the product, which could interrupt sales and adversely affect our operating results. Territories outside of the United States may require additional regulatory oversight that we may not be able to meet with our current facilities, processes and resources.

*Regulatory requirements for **Re-Tain™**:* The commercial introduction of this product in the United States requires us to obtain FDA approval. We have disclosed a timeline of events that could lead to potential product approval during the period from the fourth quarter of 2021 to the second quarter of 2022. Completing the development through to approval of the NADA by the FDA involves risk. While four of the five required Technical Sections have been approved, the development process timeline has been extensive (approximately 20 years) and has involved multiple commercial production strategies. The first-phased Chemistry, Manufacturing and Controls Technical Section was submitted for the Nisin Drug Substance during the first quarter of 2019, and the FDA response was received during the third quarter of 2019. We filed the second-phased Drug Substance and Drug Product submission during the first quarter of 2021. To reduce the risk associated with this process, we are working with Norbrook Laboratories Ltd for alignment of the required validations and Drug Product manufacture and continue to meet with the FDA to align on filing strategy and requirements. Our efforts are subject to inspection and approval by the FDA. There remains a risk that the required FDA approvals of our product and facilities could be delayed or not obtained. International regulatory approvals would be required for sales of **Re-Tain™** outside of the United States.

Economic Risks Pertaining to the Dairy and Beef Industries

The industry data referred to below is compiled from USDA databases.

Cattle count: The January count of all cattle and calves in the United States had steadily declined from 97,000,000 as of January 1, 2007 to 88,500,000 as of January 1, 2014. Then this figure increased each year to reach 94,800,000 as of January 1, 2019 before declining to 93,800,000 as of January 1, 2020 and decreasing a little further to 93,600,000 as of January 1, 2021. Reflecting seasonal trends, this figure was equal to 103,000,000 and 102,900,000 as of July 1, 2020 and 2019, respectively.

Herd size: Prior to 1957, there were over 20,000,000 cows in the U.S. dairy herd. Prior to 1986, there were over 10,000,000 cows in the U.S. dairy herd. From 1998 through 2020, the size (annual average) of the U.S. dairy herd ranged from approximately the low of 9,011,000 in 2004 to the high of 9,399,000 in 2018. This annual average dropped to 9,336,000 during 2019 and then increased to 9,388,000 during the year ended December 31, 2020. For the month of January 2021, this figure increased significantly to 9,450,000.

Milk price and feed costs: The dairy market, similar to many others, has been unstable as a result of the pandemic. The price paid to producers for milk has been very volatile. Milk was dumped on farms earlier in the year

largely because of the loss of demand for dairy products from closed restaurants and school lunch programs and other negative impacts of the pandemic, but conditions have improved since then. The Class III milk price (an industry benchmark that reflects the value of product used to make cheese) is an important indicator because it defines our customers' revenue level. This annual average milk price level (measured in dollars per hundred pounds of milk) reached its highest point (since these prices were first reported in 1980) during 2014 at $22.34 (peaking at $24.60 in September 2014), which price level has never been repeated. During 2019, this milk price average increased by 16% over 2018 to $16.96. The low price level during 2018 and into the beginning of 2019 was very challenging to the profitability of our customers. During the year ended December 31, 2020, this average milk price was equal to $18.16, but it was extremely volatile during the year due largely to disruption in demand related to the COVID-19 pandemic. The one-month fluctuation of 73% from a low of $12.14 in May to $21.04 in June set an all-time record for variability. This milk price increased significantly to $24.54 for July 2020, which is very close to the all-time record high of $24.60 set in September 2014. Projections about the milk price in 2021 are uncertain. The annual fluctuations in this milk price level are demonstrated in the following table:

Average Class III Milk Price During the Years Ended December 31,		(Decrease) Increase
2014	$22.34	
2015	$15.80	(29%)
2016	$14.87	(6%)
2017	$16.17	9%
2018	$14.61	(10%)
2019	$16.96	16%
2020	$18.16	7%

The actual level of milk prices may be less important than its level relative to feed costs. One measure of this relationship is known as the milk-to-feed price ratio, which represents the amount of feed that one pound of milk can buy. This ratio varies farm-to-farm based on individual operating parameters. The highest annual average this ratio has reached since this ratio was first reported in 1985 was 3.64 in 1987. The annual average for this ratio of 1.52 in 2012 was the lowest recorded since it was first reported in 1985. Since this ratio reached 3.24 in 2005, it has not exceeded 3.00. The annual average of 2.54 for 2014 was the highest this ratio has been since it was 2.81 in 2007. This ratio averaged 2.05 during 2018 and increased to 2.25 during 2019. This ratio increased to 2.31 during the year ended December 31, 2020. An increase in feed costs also has a negative impact on the beef industry. The following table demonstrates the annual volatility and the low values of this ratio recently:

Average Milk-To-Feed Price Ratio During the Years Ended December 31,		(Decrease) Increase
2014	2.54	
2015	2.14	(16%)
2016	2.26	6%
2017	2.42	7%
2018	2.05	(15%)
2019	2.25	10%
2020	2.31	3%

Milk cow price: The all-time high value (annual average) for a milk cow was $1,993 during 2015. Since then, this annual average value steadily declined to $1,205 during 2019 before increasing to $1,300 during 2020.

Market volatility: While the number of cows in the U.S. herd and the production of milk per cow directly influence the supply of milk, the price for milk is also influenced by very volatile international demand for milk products. Given our focus on the dairy and beef industries, the volatile market conditions and the resulting financial insecurities of our primary end users are risks to our ability to maintain and grow sales at a profitable level. These factors also heighten the challenge of selling premium-priced animal health products (such as **Tri-Shield First Defense®** and **Re-Tain™**) into the dairy market.

Small Size of Company

Dependence on key personnel: We are a small company with 61 employees (including 5 part-time employees). As such, we rely on certain key employees to support multiple operational functions, with limited redundancy in capacity. The loss of any of these key employees could adversely affect our operations until a qualified replacement is hired and trained. Our competitive position will be highly influenced by our ability to attract, retain and motivate key scientific, manufacturing, managerial and sales and marketing personnel.

Reliance on outside party to provide certain services under contract for us: We are exposed to additional regulatory compliance risks through the subcontractors that we choose to work with to produce **Re-Tain™**, who also need to satisfy certain regulatory requirements in order to provide us with the products and services we need. We are investing approximately $4 million of the additional capital we raised during the first quarter of 2019 to construct and equip our own Drug Product formulation and aseptic filling capability for **Re-Tain™** inside our existing Drug Substance facility. The objective of this investment is to end our reliance on an outside party to perform these services for us. Actual project costs could exceed our current estimates, and we could fail to access adequate funding to complete this investment if costs were to increase. Completion of this project could be delayed due to a number of factors outside our control, including delays in equipment fabrication, equipment delivery or facility construction. In addition, there is a risk that we fail to achieve regulatory approval of the new facility. We face the risk of potential supply interruption if we do not effectively manage the end of supply provided from Norbrook for orders placed by December 31, 2021 for delivery into the first half of 2022 to align with the new supply from our own formulation and aseptic filling facility which we currently expect to be operational during the fourth quarter of 2022 or second quarter of 2023.

Competition from others: Many of our competitors are significantly larger and more diversified in the relevant markets than we are and have substantially greater financial, marketing, manufacturing and human resources and more extensive product development and sales/distribution capabilities than we do, including greater ability to withstand adverse economic or market conditions and declining revenues and/or profitability. Merck and Zoetis, among other companies, sell products that compete directly with the **First Defense®** product line in preventing scours in newborn calves. The scours product sold by Zoetis sells for approximately half the price of our product, although it does not have an *E. coli* claim (which ours does). With **Tri-Shield First Defense®**, we can now compete more effectively against vaccines that are given to the mother cow (dam) to improve the quality of the colostrum that she produces for the newborn calf. Elanco, Merck and Zoetis provide these dam vaccine products to the market. There are many companies competing in the mastitis treatment market, most notably Boehringer Ingelheim, Merck and Zoetis. The subclinical mastitis products sold by these large companies are well established in the market and are priced lower than what we expect for our product, but all of them involve traditional antibiotics and are sold subject to a requirement to discard milk during and for a period of time after treatment (unlike our product that carries zero milk discard and zero milk withhold claims). There is no assurance that our products will compete successfully in these markets. We may not be aware of other companies that compete with us or intend to compete with us in the future.

Global Risks

Global COVID-19 pandemic (novel coronavirus, technically known as SARS-CoV-2): The global COVID-19 pandemic has created, and continues to create, a great deal of uncertainty for us. The positive indications about the improving health of the U.S. economy since 2008 and prior to the COVID-19 pandemic have proven to be temporary. The COVID-19 pandemic has affected international trade and created a worldwide health and economic crisis. The full impact of this viral outbreak on the global economy, and the duration of such impact, is very uncertain at this time. Stock market valuations have declined and recovered and remain volatile. There is a risk of a period of economic downturn, the severity and duration of which are difficult to know. Prior to the pandemic and the responsive federal economic stimulus programs, many feared the United States had taken on too much national debt. Now the debt load is significantly higher. The dairy market, similar to many others, has been unstable as a result of the pandemic. The price paid to producers for milk has been very volatile. Milk was dumped on farms earlier in the year largely because of the loss of demand for dairy products from closed restaurants and school lunch programs and other negative impacts of the pandemic, but conditions have improved since then. There is also economic uncertainty for beef producers, as the supply chain is interrupted or otherwise adversely affected due to closures of processing plants and reduced throughput caused by, among other things, restaurants closing or curtailing their operations. This is a very unusual situation for farmers that work so hard to improve production quality and efficiency in order to help

feed a growing population with high-quality and cost-effective proteins. A combination of the conditions, trends and concerns summarized above could have a corresponding negative effect on our business and operations, including the supply of the colostrum we purchase to produce our **First Defense®** product line, the demand for our products in the U.S. market and our ability to penetrate or maintain a profitable presence in international markets. We could experience shortages in key components and needed products, backlogs and production slowdowns due to difficulties accessing needed supplies and labor and other restrictions affecting our ability to consistently deliver our products to market. Our exposure to this risk is mitigated to some extent by the fact that our supply chain is not heavily dependent on foreign manufacturers, by our on-going cross-training of our employees, by our implementation of remote work practices (where feasible) and by our early and continued compliance with recommended hygiene and social distancing practices. Despite our best efforts and intentions, there is a risk that an employee could become infected and could infect others. This could lead to plant shutdowns and production interruptions and have other negative economic and health and safety impacts.

Bovine diseases: The potential for epidemics of bovine diseases such as Foot and Mouth Disease, Bovine Tuberculosis, Brucellosis and Bovine Spongiform Encephalopathy (BSE) presents a risk to us and our customers. Documented cases of BSE in the United States have led to an overall tightening of regulations pertaining to ingredients of animal origin, especially bovine. The **First Defense®** product line is manufactured from bovine milk (colostrum), which is not considered a BSE risk material. Future regulatory action to increase protection of the human food supply could affect the **First Defense®** product line, although presently we do not anticipate that this will be the case.

Risks Pertaining to Common Stock

Stock market valuation and liquidity: Our common stock trades on The Nasdaq Stock Market (Nasdaq: ICCC). Our average daily trading volume is lower than the volume for most other companies and the bid/ask stock price spread can be larger and prices can be volatile, which could result in investors facing difficulty selling their stock for proceeds that they may expect or desire. Our share price and average trading volume have seen a significant increase during the first quarter of 2021, but still most companies in the animal health sector have market capitalization values that greatly exceed our current market capitalization of approximately $80.6 million as of March 19, 2021. Our product sales during the year ended December 31, 2020 were $15.3 million. This means that our market valuation as of March 19, 2021 was equal to approximately 5.25 times our sales during the year ended December 31, 2020. Before gross margin from the sale of new products is achieved, our market capitalization may be heavily dependent on the perceived potential for growth from our product under development and may therefore be negatively affected by the related uncertainties and risks.

Certain provisions might discourage, delay or prevent a change in control of our Company or changes in our management: Provisions of our certificate of incorporation, our bylaws, our Common Stock Rights Plan or Delaware law may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. These provisions include:

- limitations on the removal of directors;
- advance notice requirements for stockholder proposals and nominations;
- the ability of our Board of Directors to alter or repeal our bylaws;
- the ability of our Board of Directors to refuse to redeem rights issued under our Common Stock Rights Plan or otherwise to limit or suspend its operation that would work to dilute the stock ownership of a potential hostile acquirer, potentially preventing acquisitions that have not been approved by our Board of Directors; and
- Section 203 of the Delaware General Corporation Law, which prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder (generally defined as a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder) unless the business combination is approved in a prescribed manner.

The existence of the foregoing provisions and anti-takeover measures could depress the trading price of our common stock or limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our Company, thereby reducing the likelihood of obtaining a premium for our common stock in an acquisition.

No expectation to pay any dividends or repurchase stock for the foreseeable future: We do not anticipate paying any dividends to, or repurchasing stock from, our stockholders for the foreseeable future. Instead, we expect to use cash to fund product development costs and investments in our facilities and production equipment, and to increase our working capital and to reduce debt. Stockholders must be prepared to rely on market sales of their common stock after price appreciation to earn an investment return, which may never occur. Any determination to pay dividends in the future will be made at the discretion of our Board of Directors and will depend on our financial condition, results of operations, contractual restrictions, restrictions imposed by applicable laws, current and anticipated needs for liquidity and other factors our Board of Directors deems relevant.

Possible dilution: We may need to access the capital markets again and issue additional common stock in order to fund our growth objectives, as described elsewhere in this report. Such issuances could have a dilutive effect on our existing stockholders.

Other Risks

Access to raw materials and contract manufacturing services: Our objective is to maintain more than one source of supply for the components used to manufacture and test our products that we obtain from third parties. However, there is a risk that we could have difficulty in efficiently acquiring essential supplies. We have significantly increased the number of farms from which we purchase colostrum for the **First Defense®** product line. A significant reduction in farm capacity could make it difficult for us to produce enough inventory to meet customer demand. The specific antibodies that we purify from colostrum for the **First Defense®** product line are not readily available from other sources. We are and will be dependent on our manufacturing facilities and operations in Portland for the production of the **First Defense®** product line and **Re-Tain™**. We are and will be dependent on one manufacturer for the supply of the syringes used for our gel tube formats of **Dual-Force First Defense®** and **Tri-Shield First Defense®** and one other manufacturer for the supply of syringes for **Re-Tain™**. We expect to be dependent on a contract with Norbrook for the Drug Product formulation and aseptic filling of our Nisin Drug Substance for orders placed through December 31, 2021 with deliveries extending into the first half of 2022. We expect to complete the investment to perform these services in-house during 2022 and achieve the required regulatory approval for use by the fourth quarter of 2022 or second quarter of 2023. The facility we intend to construct to perform these services in-house will be subject to FDA inspection and approval, the outcome and timing of which are not within our control. The potential alternative options for these services are narrowed considerably because our product cannot be formulated or filled in a facility that also processes traditional antibiotics (i.e., beta lactams). Any significant damage to or other disruption in the services at any of these third-party facilities or our own facilities (including due to regulatory non-approval or non-compliance) would adversely affect the production of inventory and result in significant added expenses and potential loss of future sales.

Failure to protect intellectual property: In some cases, we have chosen (and may choose in the future) not to seek patent protection for certain products or processes. Instead, we have sought (and may seek in the future) to maintain the confidentiality of any relevant proprietary technology through trade secrets, operational safeguards and contractual agreements. Reliance upon trade secret, rather than patent, protection may cause us to be vulnerable to competitors who successfully replicate (knock off) our manufacturing techniques and processes. Additionally, there can be no assurance that others may not independently develop similar trade secrets or technology or obtain access to our unpatented trade secrets or proprietary technology. Other companies may have filed patent applications and may have been issued patents involving products or technologies potentially useful to us or necessary for us to commercialize our products or achieve our business goals. If that were to be the case, there can be no assurance that we will be able to obtain licenses to such patents on terms that are acceptable to us. There is also a risk that competitors could challenge the claims in patents that have been issued to us.

Increasing dependence on the continuous and reliable operation of our information technology systems: We rely on information systems throughout our company. Any disruption of these systems or significant security breaches could adversely affect our business. Although we maintain information security policies and employ system backup measures and engage in information system redundancy planning and processes, such policies,

measures, planning and processes, as well as our current disaster recovery plan may be ineffective or inadequate to address all eventualities. As information systems and the use of software and related applications by us, our business partners, suppliers, and customers become more cloud-based, we become inherently more susceptible to cyberattacks. There has been an increase in global cybersecurity vulnerabilities and threats, including more sophisticated and targeted cyber-related attacks that pose a risk to the security of our information systems and networks and the confidentiality, availability and integrity of data and information. There are reports of increased activity by hackers and scammers during the COVID-19 pandemic. Any such attack or breach could compromise our networks and the information stored thereon could be accessed, publicly disclosed, lost, or stolen. While we have invested in our data and information technology infrastructure (including working with an information security technology consultant to assess and enhance our security systems and procedures, and periodically training our employees in such systems and procedures), there can be no assurance that these efforts will prevent a system disruption, attack, or security breach and, as such, the risk of system disruptions and security breaches from a cyberattack remains. We have not experienced any material adverse effect on our business or operations as a consequence of any such attack or breach but may incur increasing costs in performing the tasks described above. Given the unpredictability of the timing, nature and scope of such disruptions and the evolving nature of cybersecurity threats, which vary in technique and sources, if we or our business partners or suppliers were to experience a system disruption, attack or security breach that impacts any of our critical functions, or our customers were to experience a system disruption, attack or security breach via any of our connected products and services, we could potentially be subject to production downtimes, operational delays or other detrimental impacts on our operations. Furthermore, any access to, public disclosure of, or other loss of data or information (including any of our - or our customers' or suppliers' - confidential or proprietary information or personal data or information) as a result of an attack or security breach could result in governmental actions or private claims or proceedings, which could damage our reputation, cause a loss of confidence in our products and services, damage our ability to develop (and protect our rights to) our proprietary technologies and have a material adverse effect on our business, financial condition, results of operations or prospects. While this exposure is common to all companies, larger companies with greater resources may be better able to mitigate this risk than we can.

ITEM 1B — UNRESOLVED STAFF COMMENTS

None

ITEM 2 — PROPERTIES

We own a 35,000 square foot (approximately) building at 56 Evergreen Drive in Portland, Maine. We currently use this space for substantially all of our office and laboratory needs and some of our manufacturing needs for our USDA-regulated manufacturing operations. Once our capacity expansion investment for the **First Defense®** product line is completed during the second quarter of 2021, all of our powder filling, gel formulation and assembly services will be relocated out of this building, and this space will continue to be used for all of our vaccine production, liquid processing and freeze-drying operations. When we originally purchased this building in 1993, its size was 15,000 square feet, including 5,000 square feet of unfinished space on the second floor. In 2001, we completed a construction project that added approximately 5,200 square feet of new manufacturing space on the first floor and approximately 4,100 square feet of storage space on the second floor. In 2007, we built out the 5,000 square feet of unfinished space on the second floor into usable office space. After moving first floor offices into this new space on the second floor, we modified and expanded the laboratory space on the first floor and added approximately 2,500 additional square feet of storage space on the second floor. During 2009, we added 350 square feet of cold storage space connected to our first floor production area and added an additional 600 square feet to the second floor storage area. During the first quarter of 2015, we completed construction of a two-story addition connected to our facility to provide us with approximately 7,100 additional square feet for cold storage, production and warehouse space for our operations.

During the fourth quarter of 2015, we exercised an option to acquire land at 33 Caddie Lane in Portland, Maine which is near our facility at 56 Evergreen Drive, on which we initiated construction of our Drug Substance production facility for **Re-Tain™** during the third quarter of 2016. During the fourth quarter of 2017, we obtained a certificate of occupancy from the City of Portland for our 16,202 square foot (9,803 on the first floor and 6,399 on the second floor) Drug Substance production facility. Our FDA-regulated operations are conducted in this building.

During the first quarter of 2017, we purchased a 4,114 square foot facility adjacent to the Drug Substance

production facility for **Re-Tain™**. We are using this warehouse space primarily for storage of inventory, materials and equipment.

During the first quarter of 2017, we entered into a renewable, two-year lease for approximately 1,350 square feet of office, warehouse and garage space in New York to support our farm operations. This lease was extended through the end of March of 2021. During March of 2021, we entered into a renewable, two-year lease for approximately 1,300 square feet of office, storage and parking space in New York.

We are renting approximately 960 square feet in Minnesota for a sales office through at least June 2021. This lease automatically renews for one-year terms unless we or the landlord give 60-days' notice of a change.

On September 12, 2019, we entered into a lease covering approximately 14,300 square feet of office and warehouse space with a Lease Possession Date of November 15, 2019 and a Lease Commencement Date of February 13, 2020 for some of our USDA-regulated manufacturing operations. We have renovated this space to help us expand our production capacity for the **First Defense®** product line. Once our capacity expansion investment for the **First Defense®** product line is completed during the second quarter of 2021, this space will be used for all of our powder filling, gel formulation and assembly services. The lease term is ten years with a right to renew for a second ten-year term and a right of first offer to purchase. The total lease liability over the initial ten-year term (including inflationary adjustments) aggregates approximately $1.3 million before real estate and personal property taxes, utilities, insurance, maintenance and related building and operating expenses.

We maintain property insurance in amounts that approximate replacement cost and a modest amount of business interruption insurance. We also maintain access to certain animals, primarily cows as a source of colostrum used in the production of the **First Defense®** product line, through contractual relationships with commercial dairy farms.

ITEM 3 — LEGAL PROCEEDINGS

In the ordinary course of business, we may become subject to periodic lawsuits, investigations and claims. Although we cannot predict with certainty the ultimate resolution of any such lawsuits, investigations and claims against us, we do not believe that any pending or threatened legal proceedings to which we are or could become a party will have a material adverse effect on our business, results of operations, or financial condition.

ITEM 4 — MINE SAFETY DISCLOSURES

None

PART II

ITEM 5 — MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock trades on The Nasdaq Capital Market tier of The Nasdaq Stock Market under the symbol ICCC. As of March 19, 2021, we had 15,000,000 common shares authorized and 7,220,836 common shares outstanding, and there were approximately 712 shareholders of record. We have not paid dividends on our common stock and do not have any present plan or expectation to pay dividends.

Equity Compensation Plan Information

The table below summarizes the common stock reserved for issuance upon the exercise of stock options outstanding as of December 31, 2020 or that could be granted in the future:

	Number of shares to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding options	Number of shares remaining available for future issuance under stock-based compensation plans (excluding shares reflected in first column of this table)
Equity compensation plans approved by stockholders	414,000	$6.38	123,500
Equity compensation plans not approved by stockholders	—	—	—

Total	414,000	$6.38	123,500

Purchase of Equity Securities

During the fourth quarter of 2020, we accepted, as partial consideration for the exercise of stock options, the surrender of 6,583 stock options with a fair market value ranging from $5.94 to $5.99 per share at the time of exercise.

ITEM 6 — SELECTED FINANCIAL DATA

Not applicable

ITEM 7 — MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and the related notes and other financial information included in **Part II, Item 8,** "Financial Statements and Supplementary Data" of this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. One should review **Part I**, **Item 1A** — "Risk Factors" of this Annual Report for a discussion of some of the important factors that could cause actual results to differ materially from the results, objectives or expectations described in or implied by the forward-looking statements contained in the following discussion and analysis.

Liquidity and Capital Resources

Net cash provided by operating activities improved to $1.3 million during the year ended December 31, 2020 in comparison to $234,000 during the year ended December 31, 2019. Cash paid for capital expenditures was $4.1 million and $1.4 million during the years ended December 31, 2020 and 2019, respectively. Our total depreciation expense was approximately $2.3 million and $2.2 million during the years ended December 31, 2020 and 2019, respectively. We anticipate that depreciation expense, while not affecting our cash flows from operations, will result in net operating losses until and unless product sales increase sufficiently to offset these non-cash expenses. Going forward, repayments of the indebtedness incurred to fund these capital expenditures and acquire these assets will reduce our cash flows. Debt principal payments (exclusive of the $8.3 million used to repay our refinanced bank debt during the first quarter of 2020 and $624,000 used to pay down our mortgage loan during the fourth quarter of 2020) were $633,000 and $861,000 during the years ended December 31, 2020 and 2019, respectively. We are obligated to make principal repayments of approximately $768,000, $818,000 and $916,000 under these loans during the years ending December 31, 2021, 2022 and 2023, respectively.

Based on our best estimates and projections, we believe that our cash and cash equivalents, together with gross margin anticipated to be earned from ongoing product sales, will be sufficient to meet our most urgent working capital and capital expenditure requirements and to finance our ongoing business operations for at least twelve months (which is the period of time required to be addressed for such purposes by accounting disclosure standards) from the date of this filing. We have funded most of our business operations principally from the gross margin on our product sales and equity and debt financings. The table below summarizes the changes in selected, key accounts (in thousands, except for percentages):

	As of December 31,		(Decrease) Increase	
	2020	2019	Amount	%
Cash, cash equivalents and short-term investments	$7,946	$8,774	($828)	(9%)
Net working capital	$9,946	$10,694	($748)	(7%)
Total assets	$40,350	$38,692	$1,658	4%
Stockholders' equity	$28,266	$28,991	($725)	(3%)
Common shares outstanding[(1)]	7,219	7,213	6	—

(1) There were approximately 414,000 and 389,000 shares of common stock reserved for issuance for stock options that were

outstanding as of December 31, 2020 and 2019, respectively.

From the first quarter of 2016 through the first quarter of 2019, we raised gross proceeds of approximately $22.5 million (net proceeds were approximately $20.5 million) from five different common equity transactions priced between $5.25 and $7.30 per share. No warrants were issued in connection with any of these transactions, and no convertible or preferred securities were issued.

From 2010 to 2017, we secured five different debt financings with TDBank N.A., each with different maturity dates and balloon principal repayment obligations. During the first quarter of 2020, we closed on a debt refinancing aggregating $8.6 million plus a line of credit in the amount of $1.0 million with Gorham Savings Bank (GSB). This new debt was comprised of a $5.1 million mortgage loan that bears interest at a fixed rate of 3.50% per annum (with a 10-year term and 25-year amortization schedule) and a $3.5 million note that bears interest at a fixed rate of 3.50% per annum (with a 7-year term and amortization schedule). The refinancing proceeds were used to provide some additional working capital, but mostly to refinance $8.3 million of then outstanding bank debt and pay off an interest rate swap termination liability of $165,000. This debt refinancing improved our liquidity by lowering our interest expense, spreading our principal payments out over a longer time period and eliminating pending balloon principal payments that existed under some of the repaid debt. We were required to hold $1.4 million in escrow (a non-current asset), which reduced the effective availability of our liquid assets for operational needs by that amount. During the fourth quarter of 2020, we closed on a $1.5 million note with GSB that bears interest at a fixed rate of 3.5% per annum (with a 7-year term and amortization schedule). We used $624,000 of the proceeds to prepay a portion of the then outstanding principal on our mortgage loan, which reduced the then outstanding balance to 80% of the most recent appraised value of the property securing the debt, which allowed GSB to release the $1.4 million of funds held in escrow. These credit facilities are subject to certain restrictions and financial covenants and are secured by substantially all of our assets, including our facility at 56 Evergreen Drive in Portland (which was independently appraised at $4.2 million in connection with the 2015 financing and at $3 million in connection with the 2020 refinancing) and our facility at 33 Caddie Lane in Portland (which was independently appraised at $3.2 million in connection with the 2017 financing and at $2.5 million in connection with the 2020 refinancing).We are required to meet a minimum debt service coverage ratio set by GSB of 1.35. Our actual debt service coverage ratio was equal to 2.03 and 1.57 during the years ended December 31, 2020 and 2019, respectively. However, based on current projections of our future financial performance, which includes a high level of ongoing product development expenses to support **Re-Tain™**, we may not satisfy this annual requirement for the year ending December 31, 2021. We are negotiating an acceptable solution with GSB.

During June 2020, we received a $500,000 loan from the Maine Technology Institute that is subordinated to all other bank debt. The first 27 months of this loan are interest-free with no interest accrual or required principal payments. Principal and interest payments at a fixed rate of 5% per annum are due quarterly over the final five years of the loan, beginning during the fourth quarter of 2022 and continuing through the third quarter of 2027. The loan may be prepaid without penalty at any time.

Our capital expenditures during the seven-year period from January 1, 2014 to December 31, 2020 are described in the following table:

	Cash Paid During the Years Ended					
	A	B	C	D	E	Total
December 31, 2014	$1,041	$—	$—	$—	$471	$1,512
December 31, 2015	1,991	265	—	—	463	2,719
December 31, 2016	1,173	2,093	—	—	320	3,586
December 31, 2017	—	17,686	—	—	74	17,760
December 31, 2018	—	1,596	—	—	434	2,030
December 31, 2019	—	—	279	538	574	1,391
December 31, 2020	—	—	2,938	581	554	4,073
Total	$4,205	$21,640	$3,217	$1,119	$2,890	$33,071

PROJECT A (which was completed during 2016) included a 7,100 square foot facility addition at 56 Evergreen Drive and related equipment and cold storage capacity to increase the production capacity for the **First Defense®** product line. During the first quarter of 2016, we completed this investment, increasing our freeze drying

capacity by 100% and making other improvements to our liquid processing capacity, which increased our annual production capacity (in terms of annual sales dollars) to approximately $16.5 million. The actual value of this production output varies based on production yields, selling price, product format mix and other factors. This investment also included the construction and equipping of a pilot plant for small-scale Drug Substance production facility for **Re-Tain™** within our **First Defense®** production facility at 56 Evergreen. Since Project B was completed, this space has been used to produce the gel tube formats of the **First Defense®** product line. One of the objectives of Project C is to move the gel tube operations to 175 Industrial Way so that the vacated space can be used to double our liquid processing capacity at 56 Evergreen Drive.

PROJECT B (which was completed during 2018) was related to the Drug Substance production facility for **Re-Tain™** at 33 Caddie Lane. During the fourth quarter of 2017, we completed construction of the Drug Substance production facility. We began equipment installation during the third quarter of 2017, and we completed this installation during the third quarter of 2018. The total cost of this investment for the Drug Substance production facility and related processing equipment was $20.8 million plus $331,000 for the land and $472,000 for the acquisition of an adjacent 4,100 square foot warehouse facility, which is now being used for **First Defense®** operations.

PROJECT C (which we anticipate completing during the second quarter of 2021) consists of significant renovations to a 14,300 square foot leased facility at 175 Industrial Way, some facility modifications at 56 Evergreen Drive and the necessary production equipment to increase the annual production capacity of the **First Defense®** product line (in terms of annual sales dollars) from approximately $16.5 million to approximately $23 million. These production capacity projections differ moderately from prior estimates largely because of biological yield differences and changes in the product format mix. The actual value of our production output varies based on production yields, selling price, product format mix and other factors. This expansion involves a 50% increase in our freeze drying capacity and a 100% increase in our liquid processing capacity. Renovations to our leased facility at 175 Industrial Way to enable this expansion were completed during the second quarter of 2020. A site license approval for this new facility was issued by the USDA during the third quarter of 2020. By moving our powder filling and assembly services from 56 Evergreen Drive into this new space at 175 Industrial Way, we created space at 56 Evergreen Drive for the installation of the expanded freeze drying capacity. We completed that installation during the first quarter of 2021. Presently, we are completing the relocation of our gel formulation equipment from 56 Evergreen Drive to 175 Industrial Way, creating space for the doubling of our liquid processing capacity at 56 Evergreen Drive. We deferred the implementation of this final phase of the expansion project to the second quarter of 2021 in order not to disrupt finished product releases during our peak selling season. Equipment modifications and relocations of this nature require a shut down of operations for several weeks to validate the modified equipment and achieve USDA approval for its use in its new location. Since this investment was initiated during 2019 and through December 31, 2020, we paid approximately $3.2 million towards Project C, leaving an investment of approximately $300,000 to complete the investment during the second quarter of 2021. As part of this $3.5 million investment, we also have made the facility modifications necessary for a future expansion of our freeze drying capacity by an additional 33%, which would increase our annual production capacity from approximately $23 million to approximately $30 million. The equipment required to achieve this further production capacity increase would cost approximately an additional $800,000. We anticipate bringing this further expanded production capacity on-line during the second half of 2022 to meet projected growth in sales demand.

PROJECT D (construction of which we anticipate completing by the end of 2022) is a $4 million budgeted investment to bring the formulation and aseptic filling services for **Re-Tain™** Drug Product in-house to end our reliance on third-party Drug Product manufacturing services. We expect this facility to be operational during 2022. Since this investment was initiated during 2019 and through December 31, 2020, we have expended approximately $1.1 million towards Project D, leaving an investment of approximately $2.9 million to complete the project during 2021 and 2022.

PROJECT E represents other miscellaneous, routine and necessary capital investments and replacements during the years. The original budget for the year ended December 31, 2020 of $300,000 was increased to $450,000. The budget for 2021 and 2022 is $550,000 per year.

We have set aside approximately $4.3 million of the $7.9 million of the cash we had on hand as of December 31, 2020 to complete the investments in Projects C and D and to fund Project E for 2021 and 2022. We plan to complete our $3.5 million investment to increase our production capacity so that we can fill the backlog of orders,

meet ongoing demand and use any excess production to build inventory stocks by the end of 2021. This will also require that we invest some available cash in inventory. Our inventory balances were $2.1 million and $2.5 million as of December 31, 2020 and 2019, respectively. Our inventory balances consisted of approximately 1% and 21% finished goods as of December 31, 2020 and 2019, respectively. See Note 5 to the accompanying audited financial statements for more details about our inventory.

During the third quarter of 2016, the City of Portland approved a Tax Increment Financing (TIF) credit enhancement package that reduces the real estate taxes on our Drug Substance production facility for **Re-Tain™** by 65% over the eleven-year period beginning on July 1, 2017 and ending June 30, 2028 and by 30% during the year ending June 30, 2029, at which time the rebate expires. During the second quarter of 2017, the TIF was approved by the Maine Department of Economic and Community Development. The value of the tax savings will increase (decrease) in proportion to any increase (decrease) in the assessment of the building for city real estate tax purposes. The following table discloses how much of the new taxes we have generated is being relieved by the TIF and how much is being paid by ImmuCell:

Assessed Value	Twelve-Month Period Ended	Total New Taxes Generated by the Project	Less: TIF Credit	Net Amount Paid by ImmuCell
$1.7M @ April 1, 2017	June 30, 2018	$36,000	$22,000	$13,000
$4.0M @ April 1, 2018	June 30, 2019	$90,000	$58,000	$32,000
$4.0M @ April 1, 2019	June 30, 2020	$94,000	$60,000	$34,000
$4.0M @ April 1, 2020	June 30, 2021	$94,000	$60,000	$34,000

Results of Operations

Product Sales

Total product sales during the year ended December 31, 2020 increased by 12%, or $1.6 million, to $15.3 million from $13.7 million during the year ended December 31, 2019, with domestic sales increasing by 12% and international sales increasing by 11% in comparison to the year ended December 31, 2019. International sales aggregated 11% of total sales during both the years ended December 31, 2020 and 2019. The compound annual growth rate of our total product sales during the ten years ended December 31, 2020 was approximately 13%. The compound annual growth rate of our total product sales during the three years ended December 31, 2020 was approximately 18%. Sales achieved during 2020 were the equivalent of approximately 93% of the $16.5 million that we estimate to be our current annual production capacity. As of December 31, 2020, we had depleted our available finished goods inventory and had a backlog of orders worth approximately $1.8 million, compared to backlogs of approximately $130,000, $945,000, $1.4 million and $0 as of September 30, 2020, June 30, 2020, March 31, 2020 and December 31, 2019, respectively. If we had been able to ship the backlog of orders before December 31, 2020, our total sales for the year ended December 31, 2020 would have reached approximately $17.2 million. This pro-forma calculation indicates the current annual demand for our product and demonstrates the need for us to increase our annual production capacity over the current level of approximately $16.5 million (Project C, discussed above). While this is a very positive indication about the strong demand for our **First Defense®** product line, not being able to meet the needs of our customers presently could result in the loss of some customers that seek alternative scours management products during this period of short supply and may not resume purchasing our product when we have eliminated the backlog. We are missing some business during the peak season of 2021. As a result of this short supply, we anticipate that our sales during the three-month period ending March 31, 2021 will be approximately 16% lower than the sales recorded during the three-month period ended March 31, 2020. The projected sales for the first quarter of 2021 represent the equivalent of approximately 100% of the $4.1 million that we estimate to be our current quarterly production capacity. As our product mix shifts in favor of **Tri-Shield First Defense®**, it has become more difficult to achieve or exceed this estimated production capacity. After our increased production capacity comes on-line during the second quarter of 2021, and assuming we sell and produce to plan, we expect sales for the year ending December 31, 2021 to be greater than sales recorded during the year ended December 31, 2020. A precise estimation of the amount of the recovery from the first quarter sales drop to the anticipated year-over-year sales increase is very difficult to make, given the uncertainties related to the impacts of new business opportunities missed due to COVID-related restrictions and customers lost (that may be or may not return at or above prior levels of purchasing) and other factors experienced during the period of order backlog.

Investments in the **First Defense®** product line have created positive results. Sales of the **First Defense®** product line increased by 14% during the year ended December 31, 2020 in comparison to the year ended December 31, 2019, aggregating 98% and 97% of our total product sales during the years ended December 31, 2020 and 2019, respectively. Most of our growth is being realized through increased demand and a deliberate strategy to bias limited production capacity towards **Tri-Shield®** (the trivalent format of our product delivered via a gel tube), which provides broader protection to calves.

Starting in the third quarter of 2016 and through most of 2017, we had sufficient available inventory and were shipping in accordance with the demand of our distributors. However, we quickly sold out of our initial launch quantities of **Tri-Shield First Defense®** soon after regulatory approval was obtained during the fourth quarter of 2017. During most of 2018 and into the first half of 2019, we could only accept purchase orders from customers for **Tri-Shield®** to match available inventory, which required a careful allocation of product supply directly to certain end-users and veterinary clinics. Initially, production of this new product format did not keep pace with demand primarily because of our inability to produce enough of the new, complex rotavirus vaccine that is used to immunize our source cows. Work on production improvements in our vaccine laboratory throughout 2018 led to significant improvements in vaccine yield and process repeatability resolving this **Tri-Shield®** shortfall going into 2019. Allowing for the five to six month production cycle from the manufacture of our proprietary vaccine to the production of a finished dose, we were able to return to a mass market selling approach through distribution for **Tri-Shield®** during the second half of 2019. We ended the year with no backlog of orders for the **First Defense®** product line as of December, 31 2019. Our current production output was not enough to meet increasing demand for the **First Defense®** product line during 2020, and, as noted above, we ended the year with a backlog of orders worth approximately $1.8 million as of December 31, 2020. We expect to fully realize the benefits of our expanded production capacity beginning during the second quarter of 2021.

Valuation of the backlog is a non-GAAP estimate that is based on purchase orders on hand at the time that could not be met because of lack of available inventory. While we are confident that our customers would have accepted and paid for this product if it had been available to ship, we do allow customers to cancel orders, in whole or in part, to meet their current needs as time goes by. This is happening during the first quarter of 2021 and may continue to happen as we work to clear the backlog during the second quarter of 2021. Therefore, the measurement of the backlog amount is no longer a consistent indication of the amount of unmet demand for our product. As the increased production capacity comes online during the second quarter of 2021, we expect to fulfill the remaining backlog and meet ongoing strong demand. This would allow us to build inventory during the second half of 2021and return to a growth mode, as we prepare for peak season sales during the first quarter of 2022 without risk of backlog.

We are gaining market share in the United States year after year with our **Beyond Vaccination®** strategy. Our share of the market (on a unit volume basis) of scour preventative products administered at the calf-level increased to approximately 41% during 2020 (from 36% during 2019, 34% during 2018 and 32% during 2017). Our share of the market of calves treated with products administered to calves and those administered to the dam prior to calving (adjusting for two doses of dam-level scour vaccines required for primary vaccination of first-calf-heifers) increased to approximately 13% during 2020 (from 11% during 2019, 10.3% during 2018 and 9.7% during 2017). We see the potential for future market share growth in the dairy market, and we have increased our focus on the beef market.

Effective January 1, 2019, we implemented a 2% price increase for **Dual-Force®**. Effective February 1, 2020, we implemented a price increase of approximately 2% on the **First Defense®** product line (except for **Tri-Shield®** and the 90-dose bulk powder format) and **CMT**. Effective January 1, 2021, we increased our selling price of the **First Defense®** product line in the domestic market by approximately 1.6% to 3%, depending on product format, and we increased our selling price of **CMT** by almost 4%.

Sales of products other than the **First Defense®** product line decreased by 44%, or $209,000, to $270,000 during the year ended December 31, 2020 in comparison to the year ended December 31, 2019. Sales of these other products aggregated approximately 2% and 3% of our total product sales during the years ended December 31, 2020 and 2019, respectively. We sell our own **CMT** (our second leading source of product sales during 2020 and our third leading source of product sales during 2019) which is used to detect somatic cell counts in milk. We acquired a private label product (our third leading source of product sales during 2020 and our second leading source of product sales during 2019) in connection with our January 2016 acquisition of certain gel formulation technology. We have made and sold bulk reagents for Isolate™ (our fourth leading source of product sales during 2019), which is a drinking water test that is sold by our former distributor in the United Kingdom. We made one final sale of this

product to this distributor worth $134,000 during the first quarter of 2019. Because this product was non-core to our strategic focus, we sold the underlying cell line assets and intellectual property to our former distributor during the third quarter of 2018 for $700,000. We have retained the rights to all animal health, diagnostic, feed and nutritional applications of this technology.

The extent of the negative impact of the COVID-19 pandemic on the economics of our customers and on the demand for our products going forward is very difficult to assess. The Class III milk price (measured in dollars per 100 pounds) averaged $18.16 during the year ended December 31, 2020, but this price has been extremely volatile during the pandemic. For example, the price increased by 102% from a low of $12.14 during May 2020 to a recent high of $24.54 during July, which is very close to an all-time record high of $24.60 during September 2014. Initially, stay at home orders disrupted the food service supply system as schools closed and restaurants were shut down. In response, producers were forced to reduce the supply of milk to the market by drying off cows early, culling cows from the herd and dumping milk, among other tactics. Market conditions are better now, but this volatility remains a concern, and there is no way to be confident that these recent high milk prices will be sustained. The $938,000 in funding that we received from the federal government through the Paycheck Protection Program (PPP) under the CARES Act helped us maintain full employment without furloughs or layoffs and continue executing our growth plans, even though we may see a future decline in sales and gross margin as a result of the pandemic. The PPP funding created some needed financial liquidity allowing us to move forward with our investments even though we did not achieve the level of sales anticipated in our 2020 budget. After making several inquiries into different laboratories, we were able to have our antibodies tested for effectiveness against COVID-19 during the second quarter of 2020. While we understood that COVID-19 and bovine coronavirus are in different taxonomic groups, we wanted to investigate whether our antibodies could offer some cross-neutralization of COVID-19 in the laboratory testing. Unfortunately, the test results indicated, as expected, that our antibodies offered no viral neutralization activity, meaning they would be ineffective against COVID-19.

Gross Margin

Changes in our gross margin (product sales less costs of goods sold) are summarized in the following table for the respective periods (in thousands, except for percentages):

	During the Years Ended December 31,		Increase (Decrease)	
	2020	2019	Amount	%
Gross margin	$6,863	$6,740	$123	2%
Percent of product sales	45%	49%	(4%)	(9%)

The gross margin as a percentage of product sales was 45%, 49%, 47% and 50% during the years ended December 31, 2020, 2019, 2018 and 2017, respectively. The gross margin as a percentage of sales during 2020 was lower than what we normally expect, but we did increase the gross margin dollars over prior year. The gross margin percentage for the legacy format (capsule) of the **First Defense®** product line was in excess of 50%, which was in line with prior years. The **Tri-Shield®** product format is more complex (i.e. three antibodies versus two antibodies for **Dual-Force®**) and both the bivalent and trivalent gel product formats are more expensive to produce than the bolus format. These new formats are creating sales growth for us, and we are focused on increasing total gross margin dollars, even if that is accomplished with a lower gross margin as a percentage of sales. Throughout 2020, we invested significantly in equipment, infrastructure and operating expenses to increase our annual production capacity from approximately $16.5 million to approximately $23 million, but we were not able to spread the full benefit of those costs over higher production output because the increased capacity will not be on-line until the second quarter of 2021. We have estimated that this impact drove our gross margin down by a little more than a percentage point. A number of other factors contribute to the variability in our costs, resulting in some fluctuations in gross margin percentages from quarter to quarter and from year to year. Like most U.S. manufacturers, we have also been experiencing increases in the cost of labor and raw materials. We also invest to sustain compliance with current Good Manufacturing Practices (cGMP) in our production processes. Increasing production can be more expensive in the initial stages. To achieve our inventory production growth objectives, we are acquiring more raw material (colostrum) from many more cows at many new farms. As is the case with any vaccine program, animals respond less effectively to their first exposure to a new vaccine and then the effectiveness of their immune response improves in response to subsequent immunizations. As a result, during this expansion phase, similar quantities of colostrum are yielding fewer doses of finished product, which results in higher costs of goods sold. Additionally, the

biological yields from our raw material are always variable, which impacts our costs of goods sold in a similar way. Just as our customers' cows respond differently to commercial dam-level vaccines, depending on time of year and immune competency, our source cows have similar biological variances in response to our proprietary vaccines. The value of our **First Defense®** product line is that we compensate for the variability in a cow's immune response by standardizing each dose of finished product. This ensures that every calf is equally protected, which is something that dam-level commercial scours vaccines cannot offer. We continue to work on processing and yield improvements and other opportunities to reduce costs, while enhancing process knowledge and robustness. Over time, we have been able to reduce the impact of cost increases by implementing yield improvements. As we evaluate our product costs and selling price, it is one of our goals to continue to achieve a gross margin (before related depreciation and amortization expenses) as a percentage of total sales of almost 50%.

Product Development Expenses

Overview: In accordance with our budget and plans, during the year ended December 31, 2020, product development expenses increased by 18%, or $667,000, to $4.4 million in comparison to $3.7 million during the year ended December 31, 2019. Product development expenses aggregated 28% and 27% of product sales during the years ended December 31, 2020 and 2019, respectively. It is important to note that these figures include approximately $1.6 million of non-cash depreciation and stock-based compensation expenses during both the years ended December 31, 2020 and 2019. We do expect our product development expenses to decrease after **Re-Tain™** is commercialized and most of the costs incurred to maintain and run our Drug Substance production facility become part of our costs of goods sold.

*Expenses pertaining to **Re-Tain™***: The majority of our product development spending has been focused on the development of **Re-Tain™**, our purified Nisin treatment for subclinical mastitis in lactating dairy cows. Approval by the Center for Veterinary Medicine, U.S. Food and Drug Administration (FDA) of the New Animal Drug Application (NADA) for **Re-Tain™** is required before any sales of the product can be initiated. The NADA is comprised of five principal Technical Sections and one administrative submission that are subject to phased review by the FDA. By statute, each Technical Section submission is generally subject to a six-month review cycle by the FDA. Each Technical Section can be reviewed and approved separately. Upon review and assessment by the FDA that all requirements for a Technical Section have been met, the FDA may issue a Technical Section Complete Letter. The current status of our work on these submissions to the FDA is as follows:

1) Environmental Impact: During the third quarter of 2008, we received the Environmental Impact Technical Section Complete Letter from the FDA.

2) Target Animal Safety: During the second quarter of 2012, we received the Target Animal Safety Technical Section Complete Letter from the FDA.

3) Effectiveness: During the third quarter of 2012, we received the Effectiveness Technical Section Complete Letter from the FDA. The draft product label carries claims for the treatment of subclinical mastitis associated with *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus uberis*, and coagulase-negative staphylococci in lactating dairy cattle. In our pivotal effectiveness study, statistically significant cure rates were associated with a statistically significant reduction in milk somatic cell count, which is an important measure of milk quality.

4) Human Food Safety: During the third quarter of 2018, we received the Human Food Safety Technical Section Complete Letter from the FDA confirming, among other things, a zero milk discard period and a zero meat withhold period during and after treatment with our product.

5) Chemistry, Manufacturing and Controls (CMC): Having previously achieved the four different Technical Section Complete Letters from the FDA discussed above, approval of the CMC Technical Section is the fifth and final significant step required before **Re-Tain**™ product sales can be initiated in the United States. Implementing Nisin Drug Substance (the active pharmaceutical ingredient) production at our commercial facility, which is a required component of the CMC Technical Section, has been the most expensive and lengthy part of this project. We previously entered into an agreement with a multi-national pharmaceutical ingredient manufacturer for our commercial-scale supplies of Nisin. However, we determined during 2014 that the agreement did not offer us the most advantageous supply arrangement in terms of either cost or long-term dependability. We presented this product development opportunity to a variety of large and small animal health companies. While such a corporate partnership could have provided access to a much larger sales and marketing team and allowed us to avoid the large investment in a commercial-scale production facility, we concluded that a partner would have taken an unduly large

share of the gross margin from all future product sales of **Re-Tain™**. The regulatory and marketing feedback about the prospects for this product that we received from prospective partners, following their due diligence, was positive. During the third quarter of 2014, we completed an investment in facility modifications and processing equipment necessary to produce the Nisin Drug Substance at small-scale at our 56 Evergreen Drive facility. This small-scale facility was used to: i) expand our process knowledge and controls, ii) establish operating ranges for critical process parameters, iii) conduct product stability studies, iv) optimize process yields and v) verify the cost of production. We believe these efforts have reduced the risks associated with our investment in the commercial-scale Drug Substance production facility. Having raised equity during 2016 and 2017, we were able to move away from these earlier strategies and assume control over the commercial-scale manufacturing process in our own facility. During the fourth quarter of 2015, we acquired land near our existing Portland facility for the construction of a new commercial-scale Drug Substance production facility. We commenced construction of this facility during the third quarter of 2016 and completed construction during the fourth quarter of 2017. Equipment installation and qualification was initiated during the third quarter of 2017 and completed during the third quarter of 2018. Total construction and equipment costs aggregated approximately $20.8 million.

We have always believed that the fastest route to FDA approval and market launch is with the services of Norbrook Laboratories Limited of Newry, Northern Ireland (an FDA-approved Drug Product manufacturer), benefiting from their demonstrated expertise in aseptic filling. From 2010 to 2015, we had been a party to an exclusive product development and contract manufacturing agreement with Norbrook covering the Drug Product formulation, aseptic filling and final packaging services. Norbrook provided services to us under this contract throughout the FDA process for use in all of our pivotal studies. During the fourth quarter of 2015, this agreement was amended and restated to create a Product Development and Contract Manufacture Agreement (the 2015 Agreement) to, among other things, extend the term of the agreement to January 1, 2024 provided that FDA approval for commercial sales of **Re-Tain™** in the United States was obtained by December 19, 2019. It had been our expectation that we would have these services available through both the remainder of the development process to FDA approval and for approximately the first four years of commercial sales of **Re-Tain™**. Due to unexpected difficulties and delays encountered by Norbrook and the statutory FDA timeline for processing CMC Technical Sections, this December 2019 product approval target date was not achieved. During the third quarter of 2019, we entered into a Development Services and Commercial Supply Agreement (the 2019 Agreement) with Norbrook. The 2019 Agreement replaced and superseded the 2015 Agreement in its entirety. Under the 2019 Agreement, Norbrook provided the formulation, aseptic filling and final packaging services as required in order for us to submit the CMC Technical Section to the FDA. The 2019 Agreement also provides for Norbrook to perform formulation, aseptic filling and final packaging services in accordance with purchase orders that we submit from time to time for inventory build and subsequent product sales worth up to approximately $7 million for orders placed through December 31, 2021 with deliveries extending into the first half of 2022. We believe that the 2019 Agreement will enable us to commence sales of **Re-Tain**™ without delay upon receipt of the anticipated FDA approval. We intend to use the supply provided under the 2019 Agreement to bridge until our own formulation and aseptic filling capacity is available. We are in discussions with Norbrook about amending the 2019 agreement to cover some level of orders placed during 2022 in order to avoid potential interruptions in the supply of **Re-Tain™** following receipt of FDA approval and commencement of commercial sales.

Our potential alternative options for the formulation and aseptic filling services are narrowed considerably because our product cannot be formulated or filled in a facility that also processes traditional antibiotics (i.e., beta lactams). Consequently, we have decided to perform these services internally. Through a public offering of our common stock in March of 2019, we received net proceeds of approximately $8.3 million, of which approximately $4 million has been allocated to the equipping and commencement of operations of our own Drug Product formulation and aseptic filling facility. Based on current construction plans and equipment ordering and installation timelines, we expect our facility to be operational during the first half of 2022. We anticipate FDA approval of this facility during the fourth quarter of 2022 or the second quarter of 2023. This new facility will be subject to FDA inspection and approval and will have enough formulation and aseptic filling capacity to exceed the expected production capacity of our Drug Substance facility, which is at least $10 million in annual sales. This production capacity estimate is based on our assumptions as to product pricing and does not yet reflect inventory build strategies in advance of product approval or ongoing yield improvement initiatives. Establishing our own Drug Product formulation and aseptic filling capability provides us with the longer-term advantage of controlling the manufacturing process for **Re-Tain™** in one facility, thereby potentially reducing our manufacturing costs and eliminating international cold chain shipping logistics and costs. The Drug Product formulation and aseptic filling

operation will be located in existing facility space that we had intended to utilize to double our Drug Substance production capacity if warranted by sales volumes following market launch. As a result, we would need to explore alternative strategies (in parallel with ongoing Drug Substance yield improvement initiatives) to expand our Drug Substance production capacity in order to meet anticipated long-term **Re-Tain**™ sales demand. This integrated manufacturing capability for **Re-Tain**™ will substantially reduce our dependence on third parties. Upon completion of our formulation and aseptic filling facility, the only significant third-party input for **Re-Tain**™ will be the Drug Product syringes. It is anticipated that Hubert De Backer of Belgium (HDB) will supply these syringes in accordance with purchase orders that we submit. HDB is a syringe supplier for many of the largest participants in the human and veterinary medical industries, and with whom Norbrook presently works. Based on HDB's performance history and reputation in the industry, we are confident that HDB will be a dependable supplier of syringes in the quantity and of the quality needed for **Re-Tain**™. We have not yet determined if we will perform the final packaging services in-house or contract to have those services performed by a qualified third party in the United States.

The Chemistry, Manufacturing and Controls Technical Section is very complex and comprehensive. Under the FDA's phased submission process, the first-phased submission covers the Nisin Drug Substance (DS), and the second-phased submission covers the DS and the **Re-Tain**™ Drug Product (formulated DS filled in a syringe, or DP). This process allows a sponsor to respond to identified queries and/or deficiencies from the first-phased DS submission at the time of the second-phased DS and DP submission, which includes detailed information about the manufacturing process and controls for the DP. We made our first-phased DS submission during the first quarter of 2019. This submission included data from the DS Registration Batches produced at commercial scale in our new DS manufacturing facility. As part of the phased submission process, the FDA issued a Technical Section Incomplete Letter with regard to this first-phased DS submission during the third quarter of 2019 with various requests and queries in addition to referring to the fact that the second-phased DS and DP submission had yet to be submitted. We expected this response. In addition to responding to comments raised by the FDA regarding the first-phased DS submission, one of the key components of the second-phased DS and DP submission is demonstrating stability of the product over time using the commercial process and the commercial syringe in its final packaged form. We made the first submission of the second-phased DS and DP submission during the first quarter of 2021. A response from the FDA to this submission is anticipated during the third quarter of 2021 (six months after the submission date). This type of complex submission is often subject to two reviews by the FDA. We do not expect three submissions. If the FDA responds with a Technical Section Incomplete Letter, we would need time to prepare our response and then make one or more additional submissions (each subject to its own six-month review period) until the FDA is satisfied that we have adequately responded to their queries before the final 60-day administrative review period (the last step in the regulatory approval process) can be initiated. Assuming two reviews by the FDA, product approval would not be expected before the second quarter of 2022. Given the risk reduction we achieved by making the first-phased DS submission and by working with an FDA-approved DP manufacturer, it is possible that we could receive a first-time approval of the DS and DP submission during the third quarter of 2021, which could lead to FDA approval of our NADA during the fourth quarter of 2021. While being prudent with how much cash we invest into inventory that would have short expiry dating if market launch is not until the second quarter of 2022, we do intend to build some inventory during 2021 in preparation for the potential of an initial, limited market launch during the fourth quarter of 2021. We plan to continue to build more inventory during 2021 and 2022 to bridge the transition between DP supply from our contractor to our own in-house services. Our next objective is to prove the value of this new product concept as we develop a new product category. The road to commercial success for a new FDA-regulated product can be a long one for a small-cap company.

Successful FDA inspections of the manufacturing facilities must also be achieved before the NADA can be approved. During the third quarter of 2019, the FDA conducted a pre-approval inspection of our DS facility. This resulted in the issuance of certain deficiencies as identified on the FDA's Form 483. We submitted responses and data summaries in a phased manner over the fourth quarter of 2019 and first quarter of 2020. We anticipate a follow-up inspection by the FDA during the first half of 2021 to confirm the corrective actions that we have implemented. This inspection process has been managed without significant cost or impact on the timeline to product approval.

Other product development initiatives: Our second most important product development initiative (in terms of dollars invested and, we believe, potential market impact) has been focused on other improvements, extensions or additions to our **First Defense**® product line. During the second quarter of 2009, we entered into an exclusive license with the Baylor College of Medicine covering the animal health rights to the underlying rotavirus vaccine

technology that we use to generate the specific antibodies. This perpetual license (if not terminated for cause) was subject to royalty payments through December 31, 2019. We achieved product license approval and initiated market launch of this product, **Tri-Shield First Defense®**, during the fourth quarter of 2017. During the third quarter of 2018, we obtained approval from the Canadian Food Inspection Agency (CFIA) to sell **Tri-Shield®** in Canada. We initiated sales in Canada during the fourth quarter of 2019. We achieved USDA approval of our bivalent gel tube formulation (formerly marketed as **First Defense Technology®**) during the fourth quarter of 2018 and have re-branded this product format as **Dual-Force First Defense®.** During the first quarter of 2019, we obtained CFIA approval to sell the gel tube format of **Dual-Force®** in Canada and have initiated commercial sales there. We are currently working to establish USDA claims for our bivalent bulk powder formulation of **First Defense Technology®**. We are also investing in additional studies to further support the **First Defense®** product line in the market. At the same time, we are working to expand our product development pipeline of bacteriocins that can be used as alternatives to traditional antibiotics. Subject to the availability of resources, we intend to begin new development projects that are aligned with our core competencies and market focus. We also remain interested in acquiring, on suitable terms, other new products and technologies that fit with our sales focus on the dairy and beef industries.

Sales and Marketing Expenses

During the year ended December 31, 2020, sales and marketing expenses decreased by approximately 6%, or $150,000, to $2.2 million in comparison to $2.3 million during the year ended December 31, 2019, amounting to 14% and 17% of product sales during the years ended December 31, 2020 and 2019, respectively. We were able to reduce selling expenses during 2020, but we do expect these expenses to increase to approximately 20% of total product sales during 2021 as we begin to invest in the anticipated market launch of **Re-Tain™** before any new sales are realized and as in-person marketing opportunities, such as industry events, return when COVID restrictions are eased. Our budgetary guideline for 2022 and after is to keep these expenses under 20% of total sales. This ratio is expected to come down incrementally as sales grow. Our sales team has pivoted effectively to alternative selling strategies and methods during the COVID-19 pandemic to be successful at a time when most trade shows have been cancelled and travel and on-farm visitations have been limited. The reduced travel and trade show expenses and having two open sales positions (during part of the year) resulted in some cost savings. We continue to leverage the efforts of our small sales force by using animal health distributors. Sales and marketing expenses included approximately $91,000 and $109,000 of non-cash depreciation and stock-based compensation expenses during the years ended December 31, 2020 and 2019, respectively.

Administrative Expenses

During the year ended December 31, 2020, administrative expenses increased by approximately 2%, or $33,000, to just over $1.7 million in comparison to just under $1.7 million during the year ended December 31, 2019. Administrative expenses included approximately $156,000 and $208,000 of non-cash depreciation and stock-based compensation expenses during the years ended December 31, 2020 and 2019, respectively. Expenses during the first quarter of 2020 included fees paid to predecessor auditors, a new employee hiring fee and some extra legal work. We strive to be efficient with these expenses while funding costs associated with complying with the Sarbanes-Oxley Act of 2002 and all the legal, audit and other costs associated with being a publicly-held company. Prior to 2014, we had limited our investment in investor relations spending. Beginning in the second quarter of 2014, we initiated an investment in a more active investor relations program. Given travel restrictions related to the COVID-19 pandemic, this initiative has pivoted to a virtual meeting format, which is less expensive. At the same time, we continue to provide full disclosure of the status of our business and financial condition in three quarterly reports and one annual report each year, as well as in Current Reports on Form 8-K when legally required or deemed appropriate by management. These efforts may have helped us access the capital markets to fund our growth objectives. Additional information about us is available in our annual Proxy Statement. All of these reports are filed with the SEC and are available on-line or upon request to the Company.

Net Operating Loss

During the year ended December 31, 2020, our net operating loss increased by 45%, or $426,000, to $1.4 million in comparison to $954,000 during the year ended December 31, 2019. An increase of $667,000 in product development expenses (that was in line with our budgeted plans) was the largest contributor to this increase in our net operating loss.

Other (Income) Expenses, net

During the year ended December 31, 2020 other (income), net, aggregated ($348,000), which was in contrast to other expenses, net, of $314,000 during the year ended December 31, 2019. The primary cause of this change from expense to income was the recognition of $938,000 in debt forgiveness as other income, net, during the fourth quarter of 2020 from our Paycheck Protection Program (PPP) loan from the federal government received under the CARES Act. The $938,000 in PPP funding that we received during the second quarter of 2020 provided increased financial flexibility, strengthening our balance sheet with more liquidity and cash on hand, thereby enabling us to remain focused on our critical growth objectives and investments. The PPP funding has also given us the confidence to advance our $4 million investment to bring the formulation and aseptic filling services for **Re-Tain™** Drug Product in-house. This support has helped us avoid layoffs and furloughs thus far. Interest expense decreased to $413,000 during the year ended December 31, 2020 from $432,000 during the year ended December 31, 2019. Non-cash amortization of debt issuance costs was $103,000 and $17,000 during the years ended December 31, 2020 and 2019, respectively. During the year ended December 31, 2020, amortization of debt issuance costs also included the write-off of $95,000 in debt issuance costs associated with our bank debt refinancing during the first quarter of 2020. Excluding the amortization and write-off of debt issuance costs, cash-based interest expense incurred during the year ended December 31, 2020 decreased to $310,000 from $415,000 during the year ended December 31, 2019. Other income, net, during the year ended December 31, 2020 included an expense of $165,000 to terminate our interest rate swap agreements associated with our bank debt refinancing during the first quarter of 2020, which is recorded as a component of interest expense. Given the debt refinancing to fixed rate loans during the first quarter of 2020 and the refinancing we closed during the fourth quarter of 2020, we anticipate that our interest expense will be approximately $317,000, $287,000 and $258,000 during the years ending December 31, 2021, 2022 and 2023, respectively. Interest income was $27,000 and $121,000 during the years ended December 31, 2020 and 2019, respectively. Less interest income was earned during 2020 largely because we had less cash and short-term investments on hand and a lower interest rate environment. The results included a non-cash write-off of fixed assets in the amount of $39,000 during the year ended December 31, 2020 in comparison to $2,000 during 2019.

Loss Before Income Taxes

During the year ended December 31, 2020, our loss before income taxes decreased by 19%, or $235,000, to $1 million, in comparison to a loss before income taxes of $1.3 million during the year ended December 31, 2019. The largest contributor to this improvement was the $938,000 in other income recognized from the forgiveness of our Paycheck Protection Program loan from the federal government during the fourth quarter of 2020.

Income Taxes and Net Loss

During the years ended December 31, 2020 and 2019, we recorded income tax (benefit) expense of ($10,000) and $28,000, respectively. Our income tax (benefit) expense amounted to (1%) and 2% of our loss before income taxes during the years ended December 31, 2020 and 2019, respectively. Our net loss of $1 million, or $0.14 per share, during the year ended December 31, 2020 was in comparison to a net loss of $1.3 million, or $0.19 per share, during the year ended December 31, 2019.

For tax return purposes only, our depreciation expense for the Nisin Drug Substance production facility and equipment was approximately $464,000, $639,000, $9.2 million and $1.5 million for the years ended December 31, 2020, 2019, 2018 and 2017, respectively. The significant increase during 2018 was largely related to accelerated depreciation allowed for tax purposes. As of December 31, 2020, our federal net operating loss carryforward was approximately $14.6 million, which will be available to offset future taxable income. On December 22, 2017, the Tax Cuts and Jobs Act was signed into law. This legislation makes significant changes in the U.S. tax laws, including a reduction in the corporate tax rates, changes to net operating loss carryforwards and carrybacks, and a repeal of the corporate alternative minimum tax. The legislation reduced the U.S. corporate tax rate from 34% to 21%. Our income tax rate differs from this standard tax rate primarily because we are currently providing for a full valuation allowance against our deferred tax assets. While we are recording this full valuation allowance and therefore not recognizing a benefit on our tax losses, our income tax expense is largely comprised of the tax effect of the interest rate swap agreements that we terminated during the first quarter of 2020.

In addition to the above results from our Statements of Operations, we believe it is important to consider our Statements of Cash Flows in the accompanying audited financial statements to assess the cash generating ability of our operations.

Critical Accounting Policies

The financial statements are presented on the basis of accounting principles that are generally accepted in the United States. All professional accounting standards that were effective and applicable to us as of December 31, 2020 have been taken into consideration in preparing the financial statements. The preparation of financial statements requires that we make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to revenue recognition, income taxes, contingencies and the useful lives and carrying values of intangible and long lived assets. We base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We have chosen to highlight certain policies that we consider critical to the operations of our business and understanding our financial statements.

We sell products that provide **Immediate Immunity™** to newborn dairy and beef cattle. We recognize revenue in accordance with the five step model in ASC 606. These include i) identification of the contract with the customer, ii) identification of the performance obligations in the contract, iii) determination of the transaction price, iv) allocation of the transaction price to the separate performance obligations in the contract and v) recognition of revenue associated with performance obligations as they are satisfied. We recognize revenue at the time of shipment (including to distributors) for substantially all products, as title and risk of loss pass to the customer on delivery to the common carrier after concluding that collectability is reasonably assured. We do not bill for or collect sales tax because our sales are generally made to distributors and thus our sales to them are not subject to sales tax. We generally have experienced an immaterial amount of product returns.

Inventory includes raw materials, work-in-process and finished goods and is recorded at the lower of cost, on the first-in, first-out method, or net realizable value (determined as the estimated selling price in the normal course of business, less reasonably predictable costs of completion, disposal and transportation). Work-in-process and finished goods inventories include materials, labor and manufacturing overhead.

ITEM 7A — QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We believe that neither inflation, interest rates nor currency exchange rates have had a significant effect on our revenues and expenses. However, future increases in inflation or interest rates or the value of the U.S. dollar could affect our customers and the demand for our products. We hope to increase the level of our future sales of products outside the United States. The cost of our products to international customers could be affected by currency fluctuations. The decline of the U.S. dollar against other currencies could make our products less expensive to international customers. Conversely, a stronger U.S. dollar could make our products more costly for international customers. The devaluation of the dollar makes Euro-based purchases more expensive for us. We had outstanding bank debt totaling approximately $9.5 million as of December 31, 2020 that bears interest at the fixed rate of 3.5% per annum. Also, as of December 31, 2020, we had a subordinated loan from the State of Maine outstanding in the amount of $500,000 that bears no interest until the fourth quarter of 2022, at which time the note bears interest at a fixed rate of 5% per annum, unless it is repaid. See Note 10 to the accompanying audited financial statements for more details about our debt.

ITEM 8 — FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our financial statements, together with the notes thereto and the reports of the independent registered public accounting firms thereon, are set forth on Pages F-1 through F-27 at the end of this report. The index to these financial statements is as follows:

ITEM 9 — CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

On April 10, 2019, we informed RSM US LLP (RSM) that RSM had been dismissed as our independent registered public accounting firm due to our desire to work with a local firm and to obtain such services at a lower cost. This decision was authorized by our Audit Committee and ratified by our Board of Directors.

There were no disagreements between us and RSM on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of RSM, would have caused RSM to make reference to the subject matter of the disagreements in either of RSM's reports on our financial statements for the years ended December 31, 2018 or 2017. During the years ended December 31, 2018 and 2017, there were no reportable events (as defined in Item 304(a)(l)(v) of Regulation S-K), except for the material weakness in our internal control over financial reporting as disclosed in our Quarterly Reports on Forms 10-Q for the interim periods ended June 30, 2018 and September 30, 2018. None of such reports contained any adverse opinion or disclaimer or were qualified or modified as to uncertainty, audit scope or accounting principles.

On April 12, 2019, we engaged Wipfli LLP (Wipfli) as our independent registered public accounting firm for the year ending December 31, 2019 beginning with a customary review of our financial statements as of and for the quarter ended March 31, 2019. On March 20, 2020, we engaged Wipfli as our independent registered public accounting firm for the year ending December 31, 2020.

During the two most recent fiscal years and the interim periods preceding Wipfli's engagement, and through the date of their engagements, neither we nor anyone on our behalf had previously consulted with Wipfli regarding either: (a) the application of accounting principles to a specified transaction, either completed or proposed; or the type of audit opinion that might be rendered on our financial statements, and neither a written report was provided nor oral advice was provided to us that Wipfli concluded was an important factor considered by us in reaching a decision as to the accounting, auditing or financial reporting issue or (b) any matter that was either the subject of a disagreement (as defined in paragraph 304 (a)(l)(iv) of Regulation S-K and the related instructions thereto) or a reportable event (as described in paragraph 304(a)(l)(v) of Regulation S-K).

ITEM 9A — CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, with the participation of the individual who serves as our principal executive and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2020. Based on this evaluation, that officer concluded that our disclosure controls and procedures were effective as of that date. Disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

Management's Annual Report on Internal Control Over Financial Reporting

The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. We conducted an evaluation of the effectiveness of the internal controls over financial reporting based on the framework in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. This evaluation included a review of the documentation of controls, evaluation of the design effectiveness of controls, testing the operating effectiveness of the controls and a conclusion on this evaluation. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the

policies or procedures may deteriorate. Management assesses the effectiveness of the Company's internal control over financial reporting at the end of each quarter. Based on management's assessment, we believe that our internal control over financial reporting was effective as of December 31, 2020. This Annual Report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's internal control report was not subject to attestation by the Company's independent registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit the Company to provide only management's report.

Changes in Internal Controls over Financial Reporting

The individual who serves as our principal executive and principal financial officer periodically evaluates any change in internal control over financial reporting which has occurred during the prior fiscal quarter. We have concluded that there was no change in our internal control over financial reporting that occurred during the quarter or year ended December 31, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B — OTHER INFORMATION

None

PART III

ITEM 10 — DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Executive Officers of the Company

Our executive officers as of March 19, 2021 were as follows:

MICHAEL F. BRIGHAM (Age: 60, Officer since 1991, Director since 1999) was appointed to serve as President and Chief Executive Officer in February 2000, while maintaining the titles of Treasurer and Secretary, and was appointed to serve as a Director of the Company in March 1999. He previously had been elected Vice President of the Company in December 1998 and had served as Chief Financial Officer since October 1991. He has served as Secretary since December 1995 and as Treasurer since October 1991. Prior to that, he served as Director of Finance and Administration since originally joining the Company in September 1989. Mr. Brigham served as a member of the Board of Directors of the United Way of York County from 2012 to 2019, serving as its Treasurer until June 2016 and as Chair of the Board of Directors for one year and as a member of its Executive Committee. Mr. Brigham served as the Treasurer of the Board of Trustees of the Kennebunk Free Library from 2005 to 2011. He re-joined the Finance Committee of the library in 2012. Prior to joining the Company, he was employed as an audit manager for the public accounting firm of Ernst & Young. Mr. Brigham earned his Masters in Business Administration from New York University in 1989 and a Bachelor of Arts degree (with a double major in Economics and Spanish) from Trinity College in Hartford, Connecticut in 1983.

BOBBI JO BROCKMANN (Age: 44, Officer since February 2015, Director since January 2018) served as a Director of the Company from March 2017 to September 2017 and from January 2018 to the present. She was promoted to Vice President of Sales and Marketing in February 2015. She joined the Company as Director of Sales and Marketing in January 2010. Prior to that, she had been employed as Director of Sales since May 2008 and Sales Manager from February 2004 to April 2008 at APC, Inc. of Ankeny, Iowa, a developer and marketer of functional protein products for animal health and nutrition. Prior to that, she held other sales and marketing positions at APC, W & G Marketing Company, Inc. of Ames, Iowa, The Council for Agricultural Science and Technology of Ames, Iowa and Meyocks Group Advertising of West Des Moines, Iowa after graduating from Iowa State University.

JOSEPH H. CRABB, Ph.D. (Age: 66, Officer since 1996) was elected Vice President of the Company in December 1998, while maintaining the title of Chief Scientific Officer. He has served as Chief Scientific Officer since September 1998. Prior to that, he served as Vice President of Research and Development since March 1996. Prior to that, he served as Director of Research and Development and Senior Scientist since originally joining the Company in November 1988. He served as a Director of the Company from March 2001 (having previously served in that capacity from March 1999 until February 2000) until September 2017. He served as Chair of the Board of

Directors from June 2009 to February 2013. Concurrent with his employment, he has served on national study sections and advisory panels, served as a peer reviewer, and held several adjunct faculty positions. Prior to joining the Company in 1988, Dr. Crabb earned his Ph.D. in Biochemistry from Dartmouth Medical School and completed postdoctoral studies in microbial pathogenesis at Harvard Medical School, where he also served on the faculty.

ELIZABETH L. WILLIAMS (Age: 65, Officer since April 2016) joined the Company in April 2016 as Vice President of Manufacturing Operations. Previously, she led the U.S. Region for Zoetis as Vice President, Global Manufacturing and Supply. Prior to that, she held multiple Site Leader positions at Pfizer Animal Health facilities in Lincoln, Nebraska (2008-2011), Conshohocken, Pennsylvania (2006-2008) and Lee's Summit, Missouri (2003-2006). She led the manufacturing organization (1999-2003) and the Process and Product Development group (1995-1999), achieving registration, approval and successful scale-up of five new products at the Lee's Summit facility. She earned her Masters of Business Administration from Rockhurst University in Kansas City, Missouri and her Bachelor's degree in Biology from the University of Missouri.

Information with respect to our directors is incorporated herein by reference to the section of our 2021 Proxy Statement titled "Election of the Board of Directors", which we intend to file with the Securities and Exchange Commission within 120 days after December 31, 2020. There is no family relationship between any director, executive officer, or person nominated or chosen by the Company to become a director or executive officer.

ITEM 11 — EXECUTIVE COMPENSATION

Information regarding compensation paid to our executive officers is incorporated herein by reference to the section of our 2021 Proxy Statement titled "Executive Officer Compensation", which we intend to file with the Securities and Exchange Commission within 120 days after December 31, 2020.

ITEM 12 — SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Information regarding ownership of our common stock by certain owners and management is incorporated herein by reference to the section of our 2021 Proxy Statement titled “Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters”, which we intend to file with the Securities and Exchange Commission within 120 days after December 31, 2020.

ITEM 13 — CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

Information regarding certain relationships and related transactions and director independence is incorporated herein by reference to the section of our 2021 Proxy Statement titled “Certain Relationships and Related Transactions and Director Independence”, which we intend to file with the Securities and Exchange Commission within 120 days after December 31, 2020.

ITEM 14 — PRINCIPAL ACCOUNTING FEES AND SERVICES

Information regarding our principal accounting fees and services is incorporated by reference to the section of our 2021 Proxy Statement titled “Principal Accounting Fees and Services”, which we intend to file with the Securities and Exchange Commission within 120 days after December 31, 2020.

PART IV

ITEM 15 — EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

3.1	Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 of the Company's 1987 Registration Statement No. 33-12722 on Form S-1 as filed with the Commission).
3.2	Certificate of Amendment to the Company's Certificate of Incorporation effective July 23, 1990 (incorporated by reference to Exhibit 3.2 of the Company's Annual Report on Form 10-K for the year ended December 31, 2008).
3.3	Certificate of Amendment to the Company's Certificate of Incorporation effective August 24, 1992 (incorporated by reference to Exhibit 3.3 of the Company's Annual Report on Form 10-K for the year ended December 31, 2008).
3.4	Certificate of Amendment to the Company's Certificate of Incorporation effective June 16, 2016 (incorporated by reference to Exhibit 3.1 of the Company's Amended Current Report on Form 8-K/A filed on June 16, 2016).
3.5	Certificate of Amendment to the Company's Certificate of Incorporation effective June 18, 2018 (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed on June 18, 2018).
3.6	Certificate of Amendment to the Company's Certificate of Incorporation effective June 11, 2020 (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed on June 11, 2020).
3.7	Bylaws of the Company as amended (incorporated by reference to Exhibit 3.4 of the Company's Annual Report on Form 10-K for the year ended December 31, 2008).
4.1	Rights Agreement dated as of September 5, 1995, between the Company and American Stock Transfer and Trust Co., as Rights Agent, which includes as Exhibit A thereto the form of Right Certificate and as Exhibit B thereto the Summary of Rights to Purchase Common Stock (incorporated by reference to Exhibit 4.1 of the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2009).
4.1A	First Amendment to Rights Agreement dated as of June 30, 2005 (incorporated by reference to Exhibit 4.1A of the Company's Current Report on Form 8-K filed on July 5, 2005).
4.1B	Second Amendment to Rights Agreement dated as of June 30, 2008 (incorporated by reference to Exhibit 4.1A of the Company's Annual Report on Form 10-K for the year ended December 31, 2008).
4.1C	Third Amendment to Rights Agreement dated as of August 9, 2011 (incorporated by reference to Exhibit 4.1 of the Company's Quarterly Report on Form 10-Q for the three-month period ended June 30, 2011).
4.1D	Fourth Amendment to Rights Agreement dated as of June 16, 2014 (incorporated by reference to Exhibit 4.1D of the Company's Current Report on Form 8-K filed on June 17, 2014).
4.1E	Fifth Amendment to Rights Agreement dated as of April 15, 2015 (incorporated by reference to Exhibit 4.1 of the Company's Quarterly Report on Form 10-Q for the three-month period ended March 31, 2015).
4.1F	Sixth Amendment to Rights Agreement dated as of August 10, 2017 (incorporated by reference to Exhibit 4.1 of the Company's Quarterly Report on Form 10-Q for the three-month period ended June 30, 2017).
4.2*	Description of Securities Registered Under Section 12 of the Securities Exchange Act of 1934, as amended.
10.1+	Form of Indemnification Agreement (updated) entered into with each of the Company's Directors and Officers (incorporated by reference to Exhibit 10.3A of the Company's Annual Report on Form 10-KSB for the year ended December 31, 2006).
10.2+	2000 Stock Option and Incentive Plan of the Company (incorporated by reference to Exhibit 10.6 of the Company's Annual Report on Form 10-K for the year ended December 31, 2008).
10.3+	Form of Incentive Stock Agreement (incorporated by reference to Exhibit 10.7 of the Company's Annual Report on Form 10-K for the year ended December 31, 2008).
10.4+	Amendment to Employment Agreement between the Company and Michael F. Brigham dated March 26, 2010 (incorporated by reference to Exhibit 10.6 of the Company's Annual Report on Form 10-K for the year ended December 31, 2009).
10.5+	Amendment to Employment Agreement between the Company and Joseph H. Crabb dated March 26, 2010 (incorporated by reference to Exhibit 10.7 of the Company's Annual Report on Form 10-K for the year ended December 31, 2009).
10.6+	2010 Stock Option and Incentive Plan of the Company (incorporated by reference to Exhibit 10.6 of the Company's Annual Report on Form 10-K for the year ended December 31, 2010).

10.7+	Form of Incentive Stock Option Agreement (incorporated by reference to Exhibit 10.7 of the Company's Annual Report on Form 10-K for the year ended December 31, 2010).
10.8+	2017 Stock Option and Incentive Plan of the Company (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q for the three-month period ended June 30, 2017).
10.9+	Form of Incentive Stock Option Agreement (incorporated by reference to Exhibit 10.9 of the Company's Annual Report on Form 10-K for the year ended December 31, 2019).
10.10+	Incentive Compensation Agreement dated March 21, 2019 between the Company and Elizabeth L. Williams (incorporated by reference to Exhibit 10.21 of the Company's Annual Report on Form 10-K for the year ended December 31, 2019).
10.11+	Severance Agreement between the Company and Michael F. Brigham dated as of March 25, 2020 (incorporated by reference to Exhibit 10.20 of the Company's Annual Report on Form 10-K for the year ended December 31, 2019).
10.12+*	Amended and Restated Incentive Compensation Agreement between the Company and Bobbi Jo Brockmann dated as of March 29, 2021.
10.13	Development Services and Commercial Supply Agreement between the Company and Norbrook Laboratories Limited dated as of September 5, 2019 (incorporated by reference to Exhibit 99.2 of the Company's Current Report on Form 8-K filed on September 11, 2019).
10.14	Termination Agreement between the Company and Nordson Corporation dated as of September 10, 2019 (incorporated by reference to Exhibit 99.3 of the Company's Current Report on Form 8-K filed on September 11, 2019).
10.15	Indenture of Lease for Premises Located in Portland, Maine between the Company and TVP, LLC (incorporated by reference to Exhibit 99.2 of the Company's Current Report on Form 8-K filed on September 17, 2019).
10.16	Term Note for $5,100,000 between the Company and Gorham Savings Bank dated March 11, 2020 (incorporated by reference to Exhibit 99.2 of the Company's Current Report on Form 8-K filed on March 12, 2020).
10.17	Term Note for $3,500,000 between the Company and Gorham Savings Bank dated March 11, 2020 (incorporated by reference to Exhibit 99.3 of the Company's Current Report on Form 8-K filed on March 12, 2020).
10.18	Loan Agreement for $5,100,000 between the Company and Gorham Savings Bank dated March 11, 2020 (incorporated by reference to Exhibit 99.4 of the Company's Current Report on Form 8-K filed on March 12, 2020).
10.19	Loan Agreement for $3,500,000 between the Company and Gorham Savings Bank dated March 11, 2020 (incorporated by reference to Exhibit 99.5 of the Company's Current Report on Form 8-K filed on March 12, 2020.
10.20	Line of Credit Agreement for up to $1,000,000 between the Company and Gorham Savings Bank dated March 11, 2020 (incorporated by reference to Exhibit 99.6 of the Company's Current report on Form 8-K filed on March 12, 2020).
10.21	Promissory Note for $937,700 executed by the Company in favor of Gorham Savings Bank dated April 13, 2020 (incorporated by reference to Exhibit 99.2 of the Company's Current Report on Form 8-K filed on April 14, 2020).
10.22	Note Purchase Agreement executed by the Company in favor of the Maine Technology Institute dated June 12, 2020 (incorporated by reference to Exhibit 99.2 of the Company's Current Report on Form 8-K filed on June 16, 2020).
10.23	Subordinated Promissory Note for $500,000 executed by the Company in favor of the Maine Technology Institute dated June 12, 2020 (incorporated by reference to Exhibit 99.3 of the Company's Current Report on Form 8-K filed on June 16, 2020).
10.24	Term Note for $1,500,000 executed by the Company in favor of Gorham Savings Bank dated December 15, 2020 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 17, 2020).
10.25	Loan Agreement for $1,500,000 executed by the Company in favor of Gorham Savings Bank dated December 15, 2020 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on December 17, 2020).
14	Code of Business Conduct and Ethics (incorporated by reference to Exhibit 14 of the Company's Current Report on Form 8-K filed on March 20, 2014).
23.1*	Consent of Independent Registered Public Accounting Firm.
31*	Certifications Required by Rule 13a-14(a).
32*	Certification Required by Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act

of 2002.

\+ Management contract or compensatory plan or arrangement.
* Filed herewith.

101.INS XBRL Instance Document.
101.SCH XBRL Taxonomy Extension Schema Document.
101.CAL XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB XBRL Taxonomy Extension Label Linkbase Document.
101.PRE XBRL Taxonomy Extension Presentation Linkbase Document.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of ImmuCell Corporation

Opinion on the Financial Statements

We have audited the accompanying balance sheets of ImmuCell Corporation (the "Company") as of December 31, 2020 and 2019, and the related statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2020, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Valuation of Inventory

Description of the Matter	At December 31, 2020, the Company's inventory was $2,092,514. As discussed in Note 2 of the financial statements, inventory is recorded at the lower of cost, or net realizable value.

	Auditing management's valuation of inventory is complex and highly judgmental because of the estimates and assumptions used by management to determine the cost accounting and because of the variability of the cost per dose due to fluctuations in the biological yield achieved.
How We Addressed the Matter In Our Audit	The primary procedures we performed to address this critical audit matter included the following. We obtained an understanding of the cost accounting developed by management and the related assumptions and estimates used. We tested the cost accounting by examining the underlying data used by the Company to prepare the cost accounting. We evaluated the effect of the variability of the cost per dose on the inventory value by comparing the biological yield to historical results and by performing a sensitivity analysis of the potential range in inventory value within a corridor of historical results based on minimum and maximum outcomes for the biological yield.

We have served as the Company's auditor since 2019.

/s/ WIPFLI LLP

South Portland, Maine
March 30, 2021

ImmuCell Corporation

BALANCE SHEETS

	As of December 31,	
	2020	**2019**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$6,949,937	$6,293,293
Short-term investments	996,495	2,480,753
Trade accounts receivable, net	1,796,801	1,637,165
Inventory	2,092,514	2,518,256
Prepaid expenses and other current assets	321,261	259,566
Total current assets	12,157,008	13,189,033
PROPERTY, PLANT AND EQUIPMENT, net	26,754,975	25,265,738
OPERATING LEASE RIGHT-OF-USE ASSET	1,220,361	—
GOODWILL	95,557	95,557
INTANGIBLE ASSETS, net	95,520	114,624
OTHER ASSETS	26,173	26,884
TOTAL ASSETS	$40,349,594	$38,691,836
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of debt obligations	$760,337	$1,274,790
Current portion of operating lease liability	100,512	–
Accounts payable and accrued expenses	1,350,227	1,220,566
Total current liabilities	2,211,076	2,495,356
LONG-TERM LIABILITIES:		
Debt obligations, net of current portion	8,737,149	7,146,676
Operating lease liability, net of current portion	1,135,169	–
Interest rate swaps	–	58,526
Total long-term liabilities	9,872,318	7,205,202
TOTAL LIABILITIES	12,083,394	9,700,558
CONTINGENT LIABILITIES AND COMMITMENTS (See Note 11)		
STOCKHOLDERS' EQUITY:		
Common stock, $0.10 par value per share, 15,000,000 and 11,000,000 shares authorized, 7,299,009 and 7,299,009 shares issued and 7,218,836 and 7,212,919 shares outstanding, as of December 31, 2020 and 2019, respectively	729,901	729,901
Additional paid-in capital	31,372,093	31,131,893
Accumulated deficit	(3,660,402)	(2,638,285)
Treasury stock, at cost, 80,173 and 86,090 shares as of December 31, 2020 and 2019, respectively	(175,392)	(188,336)
Accumulated other comprehensive loss	—	(43,895)
Total stockholders' equity	28,266,200	28,991,278
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$40,349,594	$38,691,836

The accompanying notes are an integral part of these financial statements.

ImmuCell Corporation

STATEMENTS OF OPERATIONS

	During the Years Ended December 31,	
	2020	**2019**
Product sales	$15,342,204	$13,722,872
Costs of goods sold	8,479,378	6,983,152
Gross margin	6,862,826	6,739,720
OPERATING EXPENSES:		
Product development expenses	4,354,627	3,687,609
Sales and marketing expenses	2,167,899	2,318,112
Administrative expenses	1,720,653	1,687,907
Operating expenses	8,243,179	7,693,628
NET OPERATING LOSS	(1,380,353)	(953,908)
Other (income) expenses, net	(348,100)	313,505
LOSS BEFORE INCOME TAXES	(1,032,253)	(1,267,413)
Income tax (benefit) expense	(10,136)	28,174
NET LOSS	($1,022,117)	($1,295,587)
Basic weighted average common shares outstanding	7,213,329	6,818,960
Basic net loss per share	($0.14)	($0.19)
Diluted weighted average common shares outstanding	7,213,329	6,818,960
Diluted net loss per share	($0.14)	($0.19)

STATEMENTS OF COMPREHENSIVE LOSS

	During the Years Ended December 31,	
	2020	**2019**
Net loss	($1,022,117)	($1,295,587)
Other comprehensive income (loss):		
Interest rate swaps, before taxes	58,526	(98,735)
Income tax applicable to interest rate swaps	(14,631)	24,683
Other comprehensive income (loss), net of taxes	43,895	(74,052)
Total comprehensive loss	($978,222)	($1,369,639)

The accompanying notes are an integral part of these financial statements.

ImmuCell Corporation

STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock				Treasury Stock			
	Shares	Amount	Additional paid-in capital	Accumulated Deficit	Shares	Amount	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
BALANCE,								
December 31, 2018	5,662,645	$566,265	$22,695,557	($1,342,698)	93,683	($204,947)	$30,157	$21,744,334
Net loss	—	—	—	(1,295,587)	—	—	—	(1,295,587)
Other comprehensive loss, net of taxes	—	—	—	—	—	—	(74,052)	(74,052)
Public offering of common stock, net of $696,566 of offering costs	1,636,364	163,636	8,139,800	—	—	—	—	8,303,436
Exercise of stock options	—	—	(16,608)	—	(7,593)	16,611	—	3
Stock-based compensation	—	—	313,144	—	—	—	—	313,144
BALANCE,								
December 31, 2019	7,299,009	$729,901	$31,131,893	($2,638,285)	86,090	($188,336)	($43,895)	$28,991,278
Net loss	—	—	—	(1,022,117)	—	—	—	(1,022,117)
Other comprehensive income, net of taxes	—	—	—	—	—	—	43,895	43,895
Exercise of stock options	—	—	(12,935)	—	(5,917)	12,944	—	9
Stock-based compensation	—	—	253,135	—	—	—	—	253,135
BALANCE,								
December 31, 2020	7,299,009	$729,901	$31,372,093	($3,660,402)	80,173	($175,392)	—	$28,266,200

The accompanying notes are an integral part of these financial statements.

ImmuCell Corporation

STATEMENTS OF CASH FLOWS

	During the Years Ended December 31,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	($1,022,117)	($1,295,587)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation	2,328,179	2,248,317
Amortization of intangible assets	19,104	19,104
Amortization and write-off of debt issuance costs	102,724	16,976
Forgiveness of debt	(937,700)	—
Deferred income taxes	(14,631)	24,684
Stock-based compensation	253,135	313,144
Loss on disposal of fixed assets	39,303	2,469
Non-cash rent expense	15,320	—
Changes in:		
Trade accounts receivable	(159,636)	(704,867)
Accrued interest income	27,258	(27,753)
Inventory	425,742	(186,585)
Prepaid expenses and other current assets	(61,695)	(73,749)
Other assets	711	(13,931)
Accounts payable and accrued expenses	299,881	(88,711)
Net cash provided by operating activities	1,315,578	233,511
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(4,072,539)	(1,391,446)
Maturities of investment	3,449,000	7,670,000
Purchases of investments	(1,992,000)	(10,123,000)
Payment of contingent royalties related to 2016 acquisition	—	(8,914)
Proceeds from sale of assets	45,600	450,000
Net cash used for investing activities	(2,569,939)	(3,403,360)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from public offering, net	–	8,303,436
Proceeds from debt issuance	11,537,700	—
Debt principal repayments	(9,573,568)	(861,347)
Line of credit repayment	—	(500,000)
Payments of debt issuance costs	(53,136)	—
Proceeds from exercise of stock options	9	3
Net cash provided by financing activities	1,911,005	6,942,092
NET INCREASE IN CASH AND CASH EQUIVALENTS	656,644	3,772,243
BEGINNING CASH AND CASH EQUIVALENTS	6,293,293	2,521,050
ENDING CASH AND CASH EQUIVALENTS	$6,949,937	$6,293,293

The accompanying notes are an integral part of these financial statements

ImmuCell Corporation
STATEMENT OF CASH FLOWS
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION

	During the Years Ended December 31,	
	2020	**2019**
CASH PAID FOR:		
Income taxes	$4,581	$3,566
Interest expense	$481,408	$420,956
NON-CASH ACTIVITIES:		
Forgiveness of debt	($937,700)	$—
Change in capital expenditures included in accounts payable and accrued expenses	($170,220)	$97,530
Net change in fair value of interest rate swaps, net of taxes	($43,895)	$74,052
Operating lease right-of-use asset and operating lease liability	$1,313,698	$—

The accompanying notes are an integral part of these financial statements.

1. BUSINESS OPERATIONS

ImmuCell Corporation (the "Company", "we", "us", "our") was originally incorporated in Maine in 1982 and reincorporated in Delaware in 1987, in conjunction with our initial public offering of common stock. We are an animal health company whose purpose is to create scientifically-proven and practical products that improve the health and productivity of dairy and beef cattle. We manufacture and market the **First Defense®** product line for the prevention of scours in newborn dairy and beef calves. We are developing improved formulations of this product line providing **Immediate Immunity™** to newborn calves and are in the late stages of developing **Re-Tain™**, a treatment for cows with subclinical mastitis, the most significant cause of economic loss to the dairy industry. These products help reduce the need to use traditional antibiotics in food producing animals. We are subject to certain risks associated with this stage of development including dependence on key individuals and third-party providers of critical goods and services, competition from other larger companies, the successful sale of existing products and the development and acquisition of additional commercially viable products with appropriate regulatory approvals, where applicable.

The global COVID-19 pandemic has created, and continues to create, a great deal of uncertainty for us. The full impact of this viral outbreak on the global economy, and the duration of such impact, is very uncertain at this time. A combination of the conditions, trends and concerns could have a corresponding negative effect on our business and operations, including the supply of the colostrum we purchase to produce our **First Defense®** product line, the demand for our products in the U.S. market and our ability to penetrate or maintain a profitable presence in international markets. We could experience shortages in key components and needed products, backlogs and production slowdowns due to difficulties accessing needed supplies and labor and other restrictions affecting our ability to consistently deliver our products to market. Despite our best efforts and intentions, there is a risk that an employee could become infected and could infect others. This could lead to plant shutdowns and production interruptions and have other negative economic and health and safety impacts.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

(a) Basis of Presentation

We have prepared the accompanying audited financial statements reflecting all adjustments (which are of a normal recurring nature) that are, in our opinion, necessary in order to ensure that the financial statements are not misleading. We follow accounting standards set by the Financial Accounting Standards Board (FASB). The FASB sets generally accepted accounting principles (GAAP) that we follow to ensure we consistently report our financial condition, results of operations, earnings per share and cash flows. References to GAAP in these footnotes are to the FASB *Accounting Standards Codification*™ (Codification). Accordingly, we believe that the disclosures are adequate to ensure that the information presented is not misleading.

(b) Cash, Cash Equivalents and Short-Term Investments

We consider all highly liquid investment instruments that mature within three months of their purchase dates to be cash equivalents. Cash equivalents are principally invested in securities backed by the U.S. government. Certain cash balances in excess of Federal Deposit Insurance Corporation (FDIC) limits of $250,000 per financial institution per depositor are maintained in money market accounts at financial institutions that are secured, in part, by the Securities Investor Protection Corporation. Amounts in excess of these FDIC limits per bank that are not invested in securities backed by the U.S. government aggregated $751,050 and $5,792,993 as of December 31, 2020 and 2019, respectively. Short-term investments are classified as held to maturity and are comprised of certificates of deposit that mature in more than three months from their purchase dates and not more than twelve months from the balance sheet date. Short-term investments are held at different financial institutions that are insured by the FDIC, within the FDIC limits per financial institution. We account for investments in marketable securities in accordance with Codification Topic 320, *Investments — Debt and Equity Securities*. See Note 3.

(c) Trade Accounts Receivable, net

Accounts receivable are carried at the original invoice amount less an estimate made for doubtful collection when applicable. Management determines the allowance for doubtful accounts on a monthly basis by identifying troubled accounts and by using historical experience applied to an aging of accounts. Accounts receivable are considered to be past due if a portion of the receivable balance is outstanding for more than 30 days. Past due accounts receivable are subject to an interest charge. Accounts receivable are written off when deemed uncollectible. The amount of accounts receivable written off during all periods reported was immaterial. Recoveries of accounts receivable previously written off are recorded as income when received. As of December 31, 2020 and 2019, we determined that no allowance for doubtful accounts was necessary. See Note 4.

(d) Inventory

Inventory includes raw materials, work-in-process and finished goods and is recorded at the lower of cost, on the first-in, first-out method, or net realizable value (determined as the estimated selling price in the normal course of business, less reasonably predictable costs of completion, disposal and transportation). Work-in-process and finished goods inventories include materials, labor and manufacturing overhead. At each balance sheet date, we evaluate our ending inventories for excess quantities and obsolescence. Inventories that we consider excess or obsolete are written down to estimated net realizable value. Once inventory is written down and a new cost basis is established, it is not written back up if demand increases. We believe that supplies and raw materials for the production of our products are available from more than one vendor or farm. Our policy is to maintain more than one source of supply for the components used in our products when feasible. See Note 5.

(e) Property, Plant and Equipment

We depreciate property, plant and equipment on the straight-line method by charges to operations and costs of goods sold in amounts estimated to expense the cost of the assets from the date they are first put into service to the end of the estimated useful lives of the assets. The facility we have constructed to produce the Nisin Drug Substance for **Re-Tain™** is being depreciated over 39 years from when a certificate of occupancy was issued during the fourth quarter of 2017. We began depreciating the equipment for our Nisin Drug Substance facility when it was placed in service during the third quarter of 2018. Approximately 88% of these assets are being depreciated over ten years. We began depreciating the leasehold improvements to our new **First Defense®** production facility at 175 Industrial Way over the remainder of the ten-year lease term beginning when a certificate of occupancy was issued during the second quarter of 2020. Significant repairs to fixed assets that benefit more than a current period are capitalized and depreciated over their useful lives. Insignificant repairs are expensed when incurred. See Note 7.

(f) Intangible Assets and Goodwill

We amortize intangible assets on the straight-line method by charges to costs of goods sold in amounts estimated to expense the cost of the assets from the date they are first put into service to the end of the estimated useful lives of the assets. We have recorded intangible assets related to customer relationships, non-compete agreements and developed technology, each with defined useful lives. We have classified as goodwill the amounts paid in excess of fair value of the net assets (including tax attributes) acquired in purchase transactions. We assess the impairment of intangible assets and goodwill that have indefinite lives at the reporting unit level on an annual basis (as of December 31st) and whenever events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. We would record an impairment charge if such an assessment were to indicate that the fair value of such assets was less than the carrying value. Judgment is required in determining whether an event has occurred that may impair the value of goodwill or identifiable intangible assets. Factors that could indicate that an impairment may exist include significant under-performance relative to plan or long-term projections, significant changes in business strategy and significant negative industry or economic trends. Although we believe intangible assets and goodwill are properly stated in the accompanying financial statements, changes in strategy or market conditions could significantly impact these judgments and require an adjustment to the recorded balance. No goodwill impairments were recorded during the years ended December 31, 2020 or 2019. See Notes 2(g) and 8 for additional disclosures.

(g)Valuation of Long-Lived Assets

We periodically evaluate our long-lived assets, consisting principally of fixed assets, operating lease right-of-use asset and amortizable intangible assets, for potential impairment. In accordance with the applicable accounting guidance for the treatment of long-lived assets, we review the carrying value of our long-lived assets or asset group that is held and used, including intangible assets subject to amortization, for impairment whenever events and circumstances indicate that the carrying value of the assets may not be recoverable. Under the held for use approach, the asset or asset group to be tested for impairment should represent the lowest level for which identifiable cash flows are largely independent of the cash flows of other groups of assets and liabilities. We evaluate our long-lived assets whenever events or circumstances suggest that the carrying amount of an asset or group of assets may not be recoverable. No impairment was recognized during the years ended December 31, 2020 or 2019.

(h) Fair Value Measurements

In determining fair value measurements, we follow the provisions of Codification Topic 820, *Fair Value Measurements and Disclosures*. Codification Topic 820 defines fair value, establishes a framework for measuring fair value under GAAP and enhances disclosures about fair value measurements. The topic provides a consistent definition of fair value which focuses on an exit price, which is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The topic also prioritizes, within the measurement of fair value, the use of market-based information over entity-specific information and establishes a three-level hierarchy for fair value measurements based on the nature of inputs used in the valuation of an asset or liability as of the measurement date. As of December 31, 2020 and 2019, the carrying amounts of cash and cash equivalents, short-term investments, accounts receivable, inventory, other assets, accounts payable and accrued liabilities approximate fair value because of their short-term nature. The amount outstanding under our bank debt facilities is measured at carrying value in our accompanying balance sheets. Our bank debt facilities are valued using Level 2 inputs. The estimated fair value of our bank debt facilities approximates their carrying value based on similar instruments with similar maturities. The three-level hierarchy is as follows:

Level 1 — Pricing inputs are quoted prices available in active markets for identical assets or liabilities as of the measurement date.

Level 2 — Pricing inputs are quoted prices for similar assets or liabilities, or inputs that are observable, either directly or indirectly, for substantially the full term through corroboration with observable market data.

Level 3 — Pricing inputs are unobservable for the assets or liabilities, that is, inputs that reflect the reporting entity's own assumptions about the assumptions market participants would use in pricing the asset or liability.

In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, the level of an asset or liability within the fair value hierarchy is based on the lowest level of input that is significant to the fair value measurement. Our assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the investment. From time to time, we also hold money market mutual funds in a brokerage account, which are classified as cash equivalents and measured at fair value. The fair value of these investments is based on their closing published net asset value.

We assess the levels of the investments at each measurement date, and transfers between levels are recognized on the actual date of the event or change in circumstances that caused the transfer in accordance with our accounting policy regarding the recognition of transfers between levels of the fair value hierarchy. During the years ended December 31, 2020 and 2019, there were no transfers between levels. As of December 31, 2020 and 2019, our Level 1 assets measured at fair value by quoted prices in active markets consisted of bank savings accounts and money market funds. As of December 31, 2020 and 2019, our bank certificates of deposit were classified as Level 2 and were measured by other significant observable inputs. As of December 31, 2019, our interest rate swaps were classified as Level 2 and were measured by observable market data in combination with expected cash flows for each instrument. There were no assets or liabilities measured at fair value on a nonrecurring basis as of December 31, 2020 or 2019.

	As of December 31, 2020			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets:				
Cash and money market accounts	$6,949,937	$—	$—	$6,949,937
Bank certificates of deposit	—	996,495	—	996,495
Total	$6,949,937	$996,495	$—	$7,946,432
Liabilities:				
Bank debt	$—	($9,497,486)	$—	($9,497,486)

	As of December 31, 2019			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets:				
Cash and money market accounts	$6,293,293	$—	$—	$6,293,293
Bank certificates of deposit	—	2,480,753	—	2,480,753
Total	$6,293,293	$2,480,753	$—	$8,774,046
Liabilities:				
Interest rate swaps	$—	($58,526)	$—	($58,526)

(i) Concentration of Risk

Concentration of credit risk with respect to accounts receivable is principally limited to certain customers to whom we make substantial sales. To reduce risk, we routinely assess the financial strength of our customers and, as a consequence, believe that our accounts receivable credit risk exposure is limited. We maintain an allowance for potential credit losses when deemed necessary, but historically we have not experienced significant credit losses related to an individual customer or groups of customers in any particular industry or geographic area. Sales to significant customers that amounted to 10% or more of total product sales are detailed in the following table:

	During the Years Ended December 31,	
	2020	**2019**
Company A	41%	42%
Company B	30%	27%

Trade accounts receivable due from significant customers amounted to the percentages of total trade accounts receivable as detailed in the following table:

	As of December 31,	
	2020	**2019**
Company A	48%	28%
Company B	27%	48%

(j) Revenue Recognition

We recognize revenue in accordance with Accounting Standards Codification (ASC) 606, *Revenue from Contracts with Customers*. ASC 606 is a single comprehensive model for companies to use in accounting for revenue arising from contracts with customers. The core principle is that we recognize the amount of revenue to which we expect to be entitled for the transfer of promised goods or services to customers when a customer obtains control of

promised goods or services in an amount that reflects the consideration we expect to receive in exchange for those goods or services. In addition, the standard requires disclosure of the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. We conduct our business with customers through valid purchase orders or sales orders which are considered contracts and are not interdependent on one another. A performance obligation is a promise in a contract to transfer a distinct product to the customer. The transaction price is the amount of consideration we expect to receive under the arrangement. Revenue is measured based on consideration specified in a contract with a customer. The transaction price of a contract is allocated to each distinct performance obligation and recognized when or as the customer receives the benefit of the performance obligation. Product transaction prices on a purchase or sales order are discrete and stand-alone. We recognize revenue when we satisfy a performance obligation in a contract by transferring control over a product to a customer when product delivery occurs. Amounts due are typically paid approximately 30 days from the time control is transferred. Shipping and handling costs associated with outbound freight after control over a product has transferred to a customer are accounted for as a fulfillment cost in costs of goods sold. We do not bill for or collect sales tax because our sales are generally made to distributors and thus our sales to them are not subject to sales tax. We generally have experienced an immaterial amount of product returns. We have enhanced disclosures related to disaggregation of revenue sources and accounting policies prospectively as a result of adopting this standard. See Note 14.

(k) Expense Recognition

We do not incur costs in connection with product sales to customers that are eligible for capitalization. Advertising costs are expensed when incurred, which is generally during the month in which the advertisement is published. Advertising expenses amounted to $29,083 and $58,483 during the years ended December 31, 2020 and 2019, respectively. All product development expenses are expensed as incurred, as are all related patent costs. We capitalize costs to produce inventory during the production cycle, and these costs are charged to costs of goods sold when the inventory is sold to a customer.

(l) Income Taxes

We account for income taxes in accordance with Codification Topic 740, *Income Taxes*, which requires that we recognize a current tax liability or asset for current taxes payable or refundable and a deferred tax liability or asset for the estimated future tax effects of temporary differences and carryforwards to the extent they are realizable. During the second quarter of 2018, we assessed our historical and near-term future profitability and decided to record $563,252 in non-cash income tax expense to create a full valuation allowance against our net deferred tax assets (which consist largely of net operating loss carryforwards and federal and state tax credits). At that time, we had incurred a net loss for six consecutive quarters, had not been profitable on a year-to-date basis since the nine-month period ended September 30, 2017 and projected additional net losses for some period going forward before returning to profitability. We consider future taxable income and feasible tax planning strategies in assessing the need for a valuation allowance at each quarter end. If we determine that we would be able to realize our deferred tax assets in the future in excess of the net recorded amount over a reasonably short period of time, a reduction of the valuation allowance would increase income in the period such determination was made. Likewise, if we determine that we would not be able to realize all or part of our net deferred tax asset in the future, an increase to the valuation allowance would be charged to income in the period such determination was made.

Codification Topic 740-10 clarifies the accounting for income taxes by prescribing a minimum recognition threshold that a tax position must meet before being recognized in the financial statements. In the ordinary course of business, there are transactions and calculations where the ultimate tax outcome is uncertain. In addition, we are subject to periodic audits and examinations by the Internal Revenue Service and other taxing authorities. With few exceptions, we are no longer subject to income tax examinations by tax authorities for years before 2017. We have evaluated the positions taken on our filed tax returns. We have concluded that no uncertain tax positions existed as of December 31, 2020 or 2019. Although we believe that our estimates are reasonable, actual results could differ from these estimates. See Note 16.

(m) Stock-Based Compensation

We account for stock-based compensation in accordance with Codification Topic 718, *Compensation-Stock*

Compensation, which generally requires us to recognize non-cash compensation expense for stock-based payments using the fair-value-based method. The fair value of each stock option grant has been estimated on the date of grant using the Black-Scholes option pricing model. Accordingly, we recorded compensation expense pertaining to stock-based compensation of $253,135 and $313,144 during the years ended December 31, 2020 and 2019, respectively.

(n) Net Loss Per Common Share

Net loss per common share has been computed in accordance with Codification Topic 260-10, *Earnings Per Share*. The weighted average number of shares outstanding was 7,213,329 and 6,818,960 during the years ended December 31, 2020 and 2019, respectively. The net loss per share has been computed by dividing the net loss by the weighted average number of common shares outstanding during the period. All stock options have been excluded from the denominator in the calculation of dilutive earnings per share when we are in a loss position because their inclusion would be anti-dilutive. Outstanding stock options that were not included in this calculation because the effect would be anti-dilutive totaled 414,000 and 388,500 as of December 31, 2020 and 2019, respectively.

(o) Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. Although we regularly assess these estimates, actual amounts could differ from those estimates and are subject to change in the near term. Changes in estimates are recorded during the period in which they become known. Significant estimates include our inventory valuation, valuation of goodwill and long-lived assets, valuation of deferred tax assets, accrued expenses, costs of goods sold and useful lives of intangible assets.

(p) New Accounting Pronouncements Adopted

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*. The guidance in this ASU supersedes the leasing guidance in Topic 840, Leases. Under the new guidance, lessees are required to recognize lease assets and lease liabilities on the balance sheet for all leases with terms longer than 12 months. Leases are classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. This ASU and its amendments became effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption was permitted. We elected to adopt this ASU effective January 1, 2019. In July 2018, the FASB issued ASU 2018-10, *Codification improvements to Topic 842, Leases.* The amendments in ASU 2018-10 provide more clarification in regard to the application and requirements of Topic 842. In July 2018, the FASB issued ASU 2018-11, *Topic 842, Leases - Targeted improvements.* The amendments in ASU 2018-11 provide for the option to adopt the standard prospectively and recognize a cumulative-effect adjustment to the opening balance of retained earnings as well as offer a new practical expedient that allows us to elect, by class of underlying asset, to not separate non-lease and lease components in certain circumstances and instead to account for those components as a single item. Based on our current lease agreements and a review of all of our material vendor relationships for potential embedded lease obligations, we concluded that we were not subject to material lease obligations as of December 31, 2019, and the adoption of Topic 842 beginning did not have a material impact on our financial statements as of January 1, 2019. The lease we entered into on September 12, 2019 to expand our production capacity for the **First Defense®** product line with a Possession Date of November 15, 2019 and a Commencement Date of February 13, 2020 has been accounted for in accordance with Topic 842 beginning during the first quarter of 2020. The only material lease pursuant to which we are the lessee relates to real estate property. All leases are classified as operating leases, and therefore, were previously not recognized on our balance sheets. With the adoption of Topic 842, operating lease agreements are required to be recognized on our balance sheets as a right-of-use (ROU) asset with a corresponding lease liability. If at a lease inception date or at some later date during the term of a lease, we consider the exercising of a renewal option to be reasonably certain, we would include the extended term in the calculation of the ROU asset and lease liability. Regarding the discount rate, Topic 842 requires the use of the rate implicit in the lease whenever this rate is readily determinable. As this rate is rarely determinable, we utilize our incremental borrowing rate at lease inception, on a collateralized basis, over a similar term. See Note 12. We elected

the following practical expedients in conjunction with implementation of Topic 842:

- Inclusion of both the lease and non-lease components for all classes of underlying assets as a single component.
- Election to exclude short-term lease (i.e., lease with initial terms of twelve months or less) from capitalization on our balance sheets.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement*, which modifies the disclosure requirements of fair value measurements. Topic 820 is effective for fiscal years beginning after December 15, 2019, and early adoption is permitted. The adoption of Topic 820 did not have a material impact on our financial statements as of January 1, 2020.

We adopted ASU 2016-13, "Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments," effective January 1, 2020, using the modified retrospective transition method. This ASU amends the impairment model to utilize an expected loss methodology in place of the incurred loss methodology for financial instruments, including trade receivables and leased equipment. The amendment requires entities to consider a broader range of information to estimate expected credit losses, which may result in earlier recognition of losses. The adoption of Topic 326 did not have a material impact on our financial statements as of January 1, 2020.

(q) New Accounting Pronouncements Not Yet Adopted

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. The new guidance is intended to simplify the accounting for income taxes by removing certain exceptions and by updating accounting requirements around goodwill recognized for tax purposes and the allocation of current and deferred tax expense among legal entities, among other minor changes. ASU 2019-12 is effective for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. Early adoption is permitted. We do not expect the adoption of ASU 2019-12 to have a material impact on our financial statements.

In March 2020, the FASB issued ASU 2020-04, *Facilitation of the Effects of Reference Rate Reform on Financial Reporting*. ASU 2020-04 is intended to provide optional expedients and exceptions to the U.S. GAAP guidance on contract modifications and hedge accounting to ease the financial reporting burdens related to the discontinuation of the London Interbank Offered Rate (LIBOR) or by another reference rate expected to be discontinued. The relief offered by this guidance, if adopted, is available to companies for the period March 12, 2020 through December 31, 2022. We do not expect the discontinuation of LIBOR to have a material impact on our financial statements.

3. CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS

Cash, cash equivalents and short-term investments (at amortized cost plus accrued interest) consisted of the following:

	As of December 31, 2020	As of December 31, 2019
Cash and cash equivalents	$6,949,937	$6,293,293
Short-term investments	996,495	2,480,753
Total	$7,946,432	$8,774,046

Held to maturity securities (certificates of deposit) are carried at amortized cost. As of December 31, 2019, we were required to maintain at least $2,000,000 of otherwise unrestricted cash, cash equivalents and short-term investments in compliance with a bank debt covenant. We were not subject to such a requirement as of December 31, 2020.

4. TRADE ACCOUNTS RECEIVABLE, net

Trade accounts receivable amounted to $1,796,801 and $1,637,165 as of December 31, 2020 and 2019,

respectively. No allowance for bad debt and product returns was recorded as of December 31, 2020 or 2019.

5. INVENTORY

Inventory consisted of the following:

	As of December 31, 2020	As of December 31, 2019
Raw materials	$631,019	$791,558
Work-in-process	1,438,482	1,207,457
Finished goods	23,013	519,241
Total	$2,092,514	$2,518,256

6. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	As of December 31, 2020	As of December 31, 2019
Prepaid expenses	$252,840	$218,232
Other receivables	67,621	40,534
Security deposits	800	800
Total	$321,261	$259,566

7. PROPERTY, PLANT AND EQUIPMENT, net

Property, plant and equipment consisted of the following:

	Estimated Useful Lives (in years)	As of December 31, 2020	As of December 31, 2019
Laboratory and manufacturing equipment	3-10	$15,786,620	$15,437,724
Building and improvements	10-39	18,999,500	17,078,829
Office furniture and equipment	3-10	779,720	719,323
Construction in progress	n/a	2,337,620	1,124,189
Land	n/a	516,867	516,867
Property, plant and equipment, gross		38,420,327	34,876,932
Accumulated depreciation		(11,665,352)	(9,611,194)
Property, plant and equipment, net		$26,754,975	$25,265,738

As of December 31, 2020 and 2019, construction in progress consisted principally of payments toward the **First Defense®** production capacity expansion project and equipment needed to bring the formulation and aseptic filling for **Re-Tain™** in-house. Property, plant and equipment disposals were approximately $358,924 and $62,055 during the years ended December 31, 2020 and 2019, respectively. Depreciation expense was $2,328,179 and $2,248,317 during the years ended December 31, 2020 and 2019, respectively.

8. INTANGIBLE ASSETS

The developed technology intangible assets of $191,040 (which include an immaterial amount of value associated with customer relationships and a non-compete agreement and was valued using the relief from royalty method) are being amortized to costs of goods sold over their useful lives, which are estimated to be 10 years. Intangible amortization expense was $19,104 during both of the years ended December 31, 2020 and 2019. The net value of these intangibles was $95,520 and $114,624 as of December 31, 2020 and 2019, respectively. Intangible asset amortization expense is estimated to be $19,104 per year through December 31, 2025.

Intangible assets as of December 31, 2020 consisted of the following:

	Gross Carrying Value	Accumulated Amortization	Net Book Value
Developed technology	$184,100	($92,050)	$92,050
Customer relationships	1,300	(650)	650
Non-compete agreements	5,640	(2,820)	2,820
Total	$191,040	($95,520)	$95,520

Intangible assets as of December 31, 2019 consisted of the following:

	Gross Carrying Value	Accumulated Amortization	Net Book Value
Developed technology	$184,100	($73,640)	$110,460
Customer relationships	1,300	(520)	780
Non-compete agreements	5,640	(2,256)	3,384
Total	$191,040	($76,416)	$114,624

9. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

	As of December 31, 2020	As of December 31, 2019
Accounts payable – trade	$602,347	$401,958
Accounts payable – capital	—	170,220
Accrued payroll	525,499	399,501
Accrued professional fees	84,900	73,781
Accrued other	137,481	175,106
Total	$1,350,227	$1,220,566

10. BANK DEBT

Prior to a refinancing with Gorham Savings Bank (GSB) during the first quarter of 2020, we had in place five different credit facilities and a line of credit with TD Bank N.A. (Loans #1 to #5). During the first quarter of 2020, we closed on a debt financing with GSB aggregating $8,600,000 and a $1,000,000 line of credit. The debt is comprised of a $5,100,000 mortgage note (Loan #6) that bears interest at a fixed rate of 3.50% per annum (with a 10-year term and 25-year amortization schedule and a balloon principal payment of $3,145,888 due during the first quarter of 2030) and a $3,500,000 note (Loan #7) that bears interest at a fixed rate of 3.50% per annum (with a 7-year term and amortization schedule). The line of credit is available as needed through March 10, 2022. Interest on borrowings against the line of credit is variable at the rate of the one-month LIBOR plus 2.15% per annum. There was no outstanding balance under this line of credit as of December 31, 2020. In connection with these three credit facilities, we incurred debt issuance costs of $39,789. The amortization of debt issuance costs is being recorded as a component of interest expense, included with other (income) expenses, net, and is being amortized over the underlying terms of the two notes and the line of credit. The proceeds from the debt refinancing were used to repay all bank debt outstanding at the time of closing (Loans #1 to #5) and to provide some additional working capital. We

were required by bank debt covenant to maintain $1,400,000 in escrow (a non-current asset). During the fourth quarter of 2020, we closed on a $1,500,000 note with GSB (Loan #10) that bears interest at a fixed rate of 3.50% per annum (with a 7-year term and amortization schedule). In connection with this note, we incurred debt issuance costs of $13,347. The amortization of these debt issuance costs is also being recorded as a component of interest expense, included with other (income) expense, net, and is being amortized over the underlying term of the note. Proceeds of $624,167 were used to prepay a portion of the then outstanding principal on our mortgage loan (Loan #6), which reduced the outstanding balance to 80% of the most recent appraised value of the property securing the debt, which allowed GSB to release the $1,400,000 that had been held in escrow. The remaining proceeds were available for general working capital purposes. These three new credit facilities are secured by liens on substantially all of our assets and are subject to certain restrictions and financial covenants.

During the second quarter of 2020, we received $937,700 in support from the federal government under the Paycheck Protection Program (PPP) (Loan #8). We used the proceeds only for eligible payroll costs incurred and paid during the 24-week period beginning April 13, 2020. Our obligation to repay the principal was forgiven, and we recognized this amount as part of other (income) expenses, net, during the fourth quarter of 2020. This forgiveness of indebtedness, in accordance with the CARES Act, does not give rise to federal taxable income, and these forgiven expenses may be deducted for federal tax return purposes. The state taxability of the PPP loan forgiveness varies by tax jurisdiction.

During the second quarter of 2020, we received a $500,000 loan from the Maine Technology Institute (Loan #9) that is subordinated to all other bank debt. The first 27 months of this loan are interest-free with no interest accrual or required principal payments. Principal and interest payments at 5% per annum are due quarterly over the final five years of the loan, beginning during the fourth quarter of 2022 and continuing through the third quarter of 2027. The loan may be prepaid without penalty at any time.

Debt proceeds received and principal repayments made during the years ended December 31, 2020 and 2019 are reflected in the following tables by year and by loan:

	During the Year Ended December 31, 2020		During the Year Ended December 31, 2019	
	Proceeds from Debt Issuance	Debt Principal Repayments	Proceeds from Debt Issuance	Debt Principal Repayments
Loan #1	$—	($493,696)	$—	($68,908)
Loan #2	—	(2,143,771)	—	(89,997)
Loan #3	—	(3,236,429)	—	(562,857)
Loan #4	—	(2,336,000)	—	(128,000)
Loan #5	—	(309,182)	—	(11,585)
Loan #6	5,100,000	(720,001)	—	—
Loan #7	3,500,000	(334,489)	—	—
Loan #8[(1)]	937,700	(937,700)	—	—
Loan #9	500,000	—	—	—
Loan #10	1,500,000	—	—	—
Total	$11,537,700	($10,511,268)	$—	($861,347)

[(1)] Loan #8 was forgiven by the federal government during the fourth quarter of 2020.

Principal payments (net of debt issue costs) due under bank loans outstanding as of December 31, 2020 (excluding our $1,000,000 line of credit) are reflected in the following table by the year that payments are due:

	During the Years Ending December 31,						Total
	2021	2022	2023	2024	2025	2026 and After	
Loan #6	$116,103	$120,291	$124,629	$128,725	$133,768	$3,756,484	$4,380,000
Loan #7	460,607	477,220	494,433	512,102	530,738	690,410	3,165,510
Loan #9	—	22,160	91,446	96,104	101,001	189,289	500,000
Loan #10	191,792	198,710	205,878	213,217	220,994	469,409	1,500,000
Subtotal	768,502	818,381	916,386	950,148	986,501	5,105,592	9,545,510
Debt issuance costs	(8,165)	(6,500)	(6,093)	(6,093)	(6,093)	(15,080)	(48,024)
Total	$760,337	$811,881	$910,293	$944,055	$980,408	$5,090,512	$9,497,486

11. CONTINGENT LIABILITIES AND COMMITMENTS

Our bylaws, as amended, in effect provide that the Company will indemnify its officers and directors to the maximum extent permitted by Delaware law. In addition, we make similar indemnity undertakings to each director through a separate indemnification agreement with that director. The maximum payment that we may be required to make under such provisions is theoretically unlimited and is impossible to determine. We maintain directors' and officers' liability insurance, which may provide reimbursement to the Company for payments made to, or on behalf of, officers and directors pursuant to the indemnification provisions. Our indemnification obligations were grandfathered under the provisions of Codification Topic 460, *Guarantees*. Accordingly, we have recorded no liability for such obligations as of December 31, 2020. Since our incorporation, we have had no occasion to make any indemnification payment to any of our officers or directors for any reason.

The development, manufacturing and marketing of animal health care products entails an inherent risk that liability claims will be asserted against us during the normal course of business. We are aware of no such claims against us as of the date of this filing. We feel that we have reasonable levels of liability insurance to support our operations.

We enter into agreements with third parties in the ordinary course of business under which we are obligated to indemnify such third parties from and against various risks and losses. The precise terms of such indemnities vary with the nature of the agreement. In many cases, we limit the maximum amount of our indemnification obligations, but in some cases those obligations may be theoretically unlimited. We have not incurred material expenses in discharging any of these indemnification obligations, and based on our analysis of the nature of the risks involved, we believe that the fair value of the liabilities potentially arising under these agreements is minimal. Accordingly, we have recorded no liabilities for such obligations as of December 31, 2020.

We are committed to purchasing certain key parts (syringes) and services (formulation, aseptic filling and final packaging of Drug Product) pertaining to **Re-Tain™**, our Nisin-based intramammary treatment of subclinical mastitis in lactating dairy cows, exclusively from contractors. We are investing in the necessary equipment to perform the Drug Product formulation and aseptic filling services in-house.

During the second quarter of 2009, we entered into an exclusive and perpetual (unless terminated for cause) license with the Baylor College of Medicine covering the underlying rotavirus vaccine technology used to generate the specific antibodies for our product line extension, **Tri-Shield First Defense®**. The license was subject to a royalty equal to 4% of the sales of the **First Defense®** product line realized above the average of the sales of our bivalent product line for the years ended December 31, 2016 and 2015, plus a growth assumption of 6% per year. Earned royalties due were subject to annual minimums of $5,000, $10,000 and $15,000 for the years ending December 31, 2017, 2018 and 2019, respectively. Royalties of $76,876 were paid for the year ended December 31, 2019. No further royalties are due under this license.

During the first quarter of 2020, we entered into a Severance Agreement with our President and CEO. Under the terms of this agreement, we agree to pay this executive (or his estate) nine months of his then current salary plus any accrued and unused paid time off in the event of the involuntary termination of his employment by the Company (except for cause) or in the event of termination by him for good reason.

In addition to the commitments discussed above, we had committed $218,000 to increase our production capacity for the **First Defense®** product line, $763,000 to construct and equip our own Drug Product formulation and aseptic filling facility for **Re-Tain™**, $1,188,000 to the purchase of inventory, $123,000 to other capital expenditures and $438,000 to other obligations as of December 31, 2020.

12. OPERATING LEASE

On September 12, 2019, we entered into a lease covering approximately 14,300 square feet of office and warehouse space with a Possession Date of November 15, 2019 and a Commencement Date of February 13, 2020. The property is located at 175 Industrial Way in Portland, which is a short distance from our headquarters and manufacturing facility at 56 Evergreen Drive. We renovated this space to meet our needs in expanding our production capacity for the **First Defense®** product line. The lease term is ten years with a right to renew for a second ten-year term and a right of first offer to purchase. At this time, we are not reasonably assured that we would exercise this renewal option in place of other real estate options. A 10-year period is reflected in the right-of-use (ROU) asset and lease liability on our balance sheet. The total lease liability over the initial 10-year term (including inflationary adjustments) aggregates approximately $1,313,698 and includes real estate and personal property taxes, utilities, insurance, maintenance and related building and operating expenses. Our lease includes variable lease and non-lease components that are included in the ROU asset and lease liability. Such payments primarily include common area maintenance charges and increases in rent payments that are driven by factors such as future changes in an index, such as the Consumer Price Index. As of December 31, 2020, the balance of the operating lease ROU asset was $1,220,361 and the operating lease liability was $1,235,681. The calculated amount of the ROU asset and lease liability is impacted by the length of the lease term and the discount rate used for the present value of the minimum lease payments. The following table represents lease costs and other lease information. As we elected not to separate lease and non-lease components for all classes of underlying assets, and instead to account for them as a single lease component, the variable lease cost primarily represents variable payments such as real estate taxes and common area maintenance.

	During the Years Ended December 31,	
	2020	**2019**
Lease cost		
Operating lease cost	$104,094	—
Variable lease cost	36,523	—
Total lease cost	$140,617	—
Operating lease		
Weighted average remaining lease term (in years)	9.1	—
Weighted average discount rate	4.77%	—

Future lease payments required under non-cancelable operating leases in effect as of December 31, 2020 were as follows:

During the Years Ending December 31,	Amount
2021	$159,396
2022	162,102
2023	165,120
2024	168,210
2025	171,383
Thereafter	734,304
Total lease payments (undiscounted cash flows)	1,560,515
Less: imputed interest (discount effect of cash flows)	(324,834)
Total operating lease liabilities	$1,235,681

13. STOCKHOLDERS' EQUITY

Common Stock Issuances

From February 2016 to March 2019, we issued the aggregate of 4,037,861 shares of common stock in five different transactions raising gross proceeds of approximately $22,464,000. These funds are essential to funding our business growth plans. The details of each transaction are discussed below.

On October 28, 2015, we filed a registration statement on Form S-3 (File No. 333-207635) with the Securities and Exchange Commission (SEC) for the potential issuance of up to $10,000,000 in equity securities (subject to certain limitations). This registration statement became effective on November 10, 2015. Under this form of registration statement, we were limited within a twelve-month period to raising gross proceeds of no more than one-third of the market capitalization of our common stock (as determined by the high price of our common stock within the preceding 60 days leading up to a sale of securities) held by non-affiliates (non-insiders) of the Company. Having raised $10,000,000 in gross proceeds under the February 2016, July 2017 and December 2017 equity transactions described below, no additional equity securities can be issued under this registration statement.

On February 3, 2016, we sold 1,123,810 shares of common stock at a price to the public of $5.25 per share in an underwritten public offering pursuant to our effective shelf registration statement on Form S-3, raising gross proceeds of approximately $5,900,000 and resulting in net proceeds to the Company of approximately $5,313,000 (after deducting underwriting discounts and offering expenses incurred in connection with the equity financing).

On October 21, 2016, we closed on a private placement of 659,880 shares of common stock to nineteen institutional and accredited investors at $5.25 per share, raising gross proceeds of approximately $3,464,000 and resulting in net proceeds to the Company of approximately $3,161,000 (after deducting placement agent fees and other expenses incurred in connection with the equity financing).

On July 27, 2017, we issued 200,000 shares of our common stock at a price of $5.25 per share in a public, registered sale to two related investors pursuant to our effective shelf registration statement on Form S-3, raising gross proceeds of $1,050,000 and resulting in net proceeds of approximately $1,034,000 (after deducting expenses incurred in connection with the equity financing).

On December 21, 2017, we sold 417,807 shares of common stock at a price to the public of $7.30 per share in an underwritten public offering pursuant to our effective shelf registration statement on Form S-3, raising gross proceeds of approximately $3,050,000 and resulting in net proceeds to the Company of approximately $2,734,000 (after deducting underwriting discounts and offering expenses incurred in connection with the equity financing).

On November 20, 2018, we filed a registration statement on Form S-3 (File No. 333-228479) with the Securities and Exchange Commission (SEC) for the potential issuance of up to $20,000,000 in equity securities (subject to certain limitations). This registration statement became effective on November 29, 2018. Under this form of registration statement, we are limited within a twelve-month period to raising gross proceeds of no more than one-third of the market

capitalization of our common stock (as determined by the high price of our common stock within the preceding 60 days leading up to a sale of securities) held by non-affiliates (non-insiders) of the Company.

On March 29, 2019, we sold 1,636,364 shares of common stock at a price to the public of $5.50 per share in an underwritten public offering pursuant to our effective shelf registration statement on Form S-3, raising gross proceeds of approximately $9,000,000 and resulting in net proceeds to the Company of approximately $8,303,000 (after deducting underwriting discounts and offering expenses incurred in connection with the equity financing).

Stock Option Plans

In June 2000, our stockholders approved the 2000 Stock Option and Incentive Plan (the "2000 Plan") pursuant to the provisions of the Internal Revenue Code of 1986, under which employees and certain service providers may be granted options to purchase shares of the Company's common stock at i) no less than fair market value on the date of grant in the case of incentive stock options and ii) no less than 85% of fair market value on the date of grant in the case of non-qualified stock options. Vesting requirements are determined by the Compensation and Stock Option Committee of the Board of Directors on a case by case basis. Originally, 250,000 shares of common stock were reserved for issuance under the 2000 Plan. The stockholders of the Company approved an increase in this number to 500,000 shares in June 2001. All options granted under the 2000 Plan expire no later than ten years from the date of grant. The 2000 Plan expired in February 2010, after which date no further options could be granted under the 2000 Plan. As of December 31, 2019, no options were outstanding under the 2000 Plan.

In June 2010, our stockholders approved the 2010 Stock Option and Incentive Plan (the "2010 Plan") pursuant to the provisions of the Internal Revenue Code of 1986, under which employees and certain service providers may be granted options to purchase shares of the Company's common stock at no less than fair market value on the date of grant. At that time, 300,000 shares of common stock were reserved for issuance under the 2010 Plan and subsequently no additional shares have been reserved for the 2010 Plan. Vesting requirements are determined by the Compensation and Stock Option Committee of the Board of Directors on a case by case basis. All options granted under the 2010 Plan expire no later than ten years from the date of grant. The 2010 Plan expired in June 2020, after which date no further options can be granted under the 2010 Plan. However, options outstanding under the 2010 Plan at that time can be exercised in accordance with their terms. As of December 31, 2020, there were 237,500 options outstanding under the 2010 Plan.

In June 2017, our stockholders approved the 2017 Stock Option and Incentive Plan (the "2017 Plan") pursuant to the provisions of the Internal Revenue Code of 1986, under which employees and certain service providers may be granted options to purchase shares of the Company's common stock at no less than fair market value on the date of grant. At that time, 300,000 shares of common stock were reserved for issuance under the 2017 Plan and subsequently no additional shares have been reserved for the 2017 Plan. Vesting requirements are determined by the Compensation and Stock Option Committee of the Board of Directors on a case by case basis. All options granted under the 2017 Plan expire no later than ten years from the date of grant. The 2017 Plan expires in March 2027, after which date no further options can be granted under the 2017 Plan. However, options outstanding under the 2017 Plan at that time can be exercised in accordance with their terms. As of December 31, 2020, there were 176,500 options outstanding under the 2017 Plan.

Activity under the stock option plans described above was as follows:

	2000 Plan	2010 Plan	2017 Plan	Weighted Average Exercise Price	Aggregate Intrinsic Value[(1)]
Outstanding as of December 31, 2018	12,500	270,000	111,500	$6.37	$266,020
Grants	—	26,000	25,000	$5.90	
Terminations	—	(26,000)	(3,000)	$6.05	
Exercises	(12,500)	(15,000)	—	$4.37	
Outstanding as of December 31, 2019	—	255,000	133,500	$6.48	($516,475)
Grants	—	7,000	93,000	$5.03	
Terminations	—	(12,000)	(50,000)	$5.45	
Exercises	—	(12,500)	—	$3.15	
Outstanding as of December 31, 2020	—	237,500	176,500	$6.38	($180,038)
Vested as of December 31, 2020	—	156,000	10,000	$6.31	($59,290)
Vested and expected to vest as of December 31, 2020	—	237,500	176,500	$6.38	($180,038)
Reserved for future grants	—	—	123,500		

(1) Intrinsic value is the difference between the fair market value as of the date indicated and as of the date of the option grant (which is equal to the option exercise price).

The following table displays additional information about the stock option plans described above:

	Number of Shares	Weighted Average Fair Value at Grant Date	Weighted Average Exercise Price
Non-vested stock options as of January 1, 2020	321,000	$3.49	$6.55
Non-vested stock options as of December 31, 2020	248,000	$3.25	$6.44
Stock options granted during the year ended December 31, 2020	100,000	$2.47	$5.03
Stock options that vested during the year ended December 31, 2020	113,000	$3.48	$6.06
Stock options that were forfeited during the year ended December 31, 2020	62,000	$2.84	$5.45

During the year ended December 31, 2020, two employees exercised stock options covering 12,500 shares by the surrender of 6,583 stock options with a fair market value of the underlying common stock equal to $39,366 at the time of exercise and $9 in cash. During the year ended December 31, 2019, one director and two employees exercised stock options covering 27,500 shares by the surrender of 19,907 stock options with a fair market value of the underlying common stock equal to $120,172 at the time of exercise and $3 in cash.

The weighted average remaining life of the options outstanding under the 2010 Plan and the 2017 Plan as of December 31, 2020 was approximately 5 years and 9 months. The weighted average remaining life of the options exercisable under these plans as of December 31, 2020 was approximately 5 years and 6 months. The exercise prices of the options outstanding as of December 31, 2020 ranged from $4.00 to $8.90 per share. The 100,000 stock options granted during the year ended December 31, 2020 had exercise prices between $4.00 and $6.37 per share. The 51,000 stock options granted during the year ended December 31, 2019 had exercise prices between $5.175 and $7.50 per share. The aggregate intrinsic value of options exercised during 2020 and 2019 approximated $35,375 and $46,091, respectively. The weighted-average grant date fair values of options granted during 2020 and 2019 were $2.47 and $2.93, respectively. As of December 31, 2020, total unrecognized stock-based compensation related to non-vested stock options aggregated $212,490, which will be recognized over a weighted average remaining period of 1 year and 3 months. The fair value of each stock option grant has been estimated on the date of grant using the Black-Scholes option pricing model, for the purpose discussed in Note 2(m), with the following weighted-average assumptions for the years ended December 31, 2020 and 2019:

	During the Years Ended December 31,	
	2020	**2019**
Risk-free interest rate	0.41%	1.9%
Dividend yield	0%	0%
Expected volatility	53%	51%
Expected life	6.1 years	6 years

The risk-free interest rate is based on U.S. Treasury yields for a maturity approximating the expected option term, while the other assumptions are derived from averages of our historical data.

Common Stock Rights Plan

In September 1995, our Board of Directors adopted a Common Stock Rights Plan (the "Rights Plan") and declared a dividend of one common share purchase right (a "Right") for each of the then outstanding shares of the common stock of the Company. Each Right entitles the registered holder to purchase from the Company one share of common stock at an initial purchase price of $70.00 per share, subject to adjustment. The description and terms of the Rights are set forth in a Rights Agreement between the Company and American Stock Transfer & Trust Co., as Rights Agent.

The Rights (as amended) become exercisable and transferable apart from the common stock upon the earlier of i) 10 days following a public announcement that a person or group (Acquiring Person) has, without the prior consent of the Continuing Directors (as such term is defined in the Rights Agreement), acquired beneficial ownership of 20% or more of the outstanding common stock or ii) 10 days following commencement of a tender offer or exchange offer the consummation of which would result in ownership by a person or group of 20% or more of the outstanding common stock (the earlier of such dates being called the Distribution Date).

Upon the Distribution Date, the holder of each Right not owned by the Acquiring Person would be entitled to purchase common stock at a discount to the initial purchase price of $70.00 per share, effectively equal to one half of the market price of a share of common stock on the date the Acquiring Person becomes an Acquiring Person. If, after the Distribution Date, the Company should consolidate or merge with any other entity and the Company were not the surviving company, or, if the Company were the surviving company, all or part of the Company's common stock were changed or exchanged into the securities of any other entity, or if more than 50% of the Company's assets or earning power were sold, each Right would entitle its holder to purchase, at the Rights' then-current purchase price, a number of shares of the acquiring company's common stock having a market value at that time equal to twice the Right's exercise price.

At any time after a person or group becomes an Acquiring Person and prior to the acquisition by such person or group of 50% or more of the outstanding common stock, the Board of Directors of the Company may exchange the Rights (other than Rights owned by such person or group which have become void), in whole or in part, at an exchange ratio of one share of common stock per Right (subject to adjustment). At any time prior to 14 days following the date that any person or group becomes an Acquiring Person (subject to extension by the Board of Directors), the Board of Directors of the Company may redeem the then outstanding Rights in whole, but not in part, at a price of $0.005 per Right, subject to adjustment.

At various times over the years, our Board of Directors has voted to authorize amendments of the Rights Agreement to extend the Final Expiration Date, which is currently September 19, 2022. Our Board of Directors also has voted to authorize amendments to increase the ownership threshold for determining "Acquiring Person" status to 20%. During the second quarter of 2015, our Board of Directors also voted to authorize an amendment to remove a provision that prevented a new group of directors elected following the emergence of an Acquiring Person (an owner of more than 20% of our stock) from controlling the Rights Plan by maintaining exclusive authority over the Rights Plan with pre-existing directors. We did this because such provisions have come to be viewed with disfavor by Delaware courts. Each time that we made such amendments we entered into amendments to the Rights Agreement with the Rights Agent reflecting such extensions, threshold increases or provision changes. No other changes have been made to the terms of the Rights or the Rights Agreement.

Authorized Common Stock

At the June 14, 2018 Annual Meeting of Stockholders, our stockholders voted to approve an amendment to our Certificate of Incorporation to increase the number of shares of common stock authorized for issuance from 8,000,000 to 11,000,000. At the June 10, 2020 Annual Meeting of Stockholders, our stockholders voted to approve an amendment to our Certificate of Incorporation to increase the number of shares of common stock authorized for issuance from 11,000,000 to 15,000,000.

14. REVENUE

We primarily offer the **First Defense®** product line to dairy and beef producers to prevent scours in newborn calves. Generally, our products are promoted to veterinarians as well as dairy and beef producers by our sales team and then sold through distributors. Our primary market is North America. We do sell into select international regions and may expand this international reach in the future. There were no material changes between the allocation and timing of revenue recognition during the years ended December 31, 2020 and 2019. We do not have any contract assets for which we have satisfied the performance obligations but do not yet have the right to bill for or contract liabilities such as customer advances. All trade receivables on our balance sheets are from contracts with customers. We incur no material costs to obtain contracts.

	During the Years Ended December 31,			
	2020	%	2019	%
United States	$13,644,768	89%	$12,191,108	89%
Other[(1)]	1,697,436	11%	1,531,764	11%
Total product sales	$15,342,204	100%	$13,722,872	100%

The following table presents our product sales disaggregated by geographic area:

[(1)] Sales outside of the United States included $133,601 of non-animal health sales during the first quarter of 2019, which product has since been divested.

The following table presents our product sales disaggregated by major product category:

	During the Years Ended December 31,			
	2020	%	2019	%
First Defense® product line	$15,072,446	98%	$13,244,396	97%
Other animal health	269,758	2%	344,875	2%
Other	—	—	133,601	1%
Total product sales	$15,342,204	100%	$13,722,872	100%

15. OTHER (INCOME) EXPENSES, NET

Other (income) expenses, net, consisted of the following:

	During the Years Ended December 31,	
	2020	2019
Interest expense[(1)]	$412,687	$431,788
Interest rate swap termination fee	165,050	—
Debt forgiveness	(937,700)	—
Loss on disposal of fixed assets	39,303	2,469
Interest income	(27,440)	(120,752)
Other (income) expenses, net	($348,100)	$313,505

[(1)] Interest expense during 2020 included a $94,782 write-off of debt issuance costs associated with debt that we repaid during the first quarter of 2020. Interest expense included $7,942 and $16,976 in amortization of debt issuance costs during the years ended December 31, 2020 and 2019, respectively.

16. INCOME TAXES

Our income tax (benefit) expense aggregated ($10,136) and $28,174 (amounting to (1%) and 2% of our loss before income taxes, respectively) for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had federal net operating loss carryforwards of $14,642,294 of which $12,930,387 do not expire and $1,711,907 which expire in 2034 through 2037 (if not utilized before then) and state net operating loss carryforwards of $2,647,292 that expire in 2037 through 2038 (if not utilized before then). Additionally, we had federal general business tax credit carryforwards of $490,018 that expire in 2027 through 2039 (if not utilized before then) and state tax credit carryforwards of $763,350 that expire in 2023 through 2039 (if not utilized before then).

The provision for income taxes is determined using the asset and liability approach of accounting for income taxes. Under this approach, deferred taxes represent the estimated future tax effects of temporary differences between book and tax treatment of assets and liabilities and carryforwards to the extent they are realizable. During the second quarter of 2018, we assessed our historical and near-term future profitability and recorded $563,252 in non-cash income tax expense to create a full valuation allowance against our net deferred tax assets (which consist largely of net operating loss carryforwards and federal and state credits) based on applicable accounting standards and practices. At that time, we had incurred a net loss for six consecutive quarters, had not been profitable on a year-to-date basis since the nine-month period ended September 30, 2017 and projected additional net losses for some period going forward before returning to profitability. Should future profitability be realized at an adequate level, we would be able to release this valuation allowance (resulting in a non-cash income tax benefit) and realize these deferred tax assets before they expire. We will continue to assess the need for the valuation allowance at each quarter and, in the event that actual results differ from these estimates, or we adjust these estimates in future periods, we may need to adjust our valuation allowance. Adjustments related to the termination of our interest rate swap agreements were recorded during the first quarter of 2020. No subsequent adjustments were recorded.

Net operating loss carryforwards, credits, and other tax attributes are subject to review and possible adjustment by the Internal Revenue Service. Section 382 of the Internal Revenue Code contains provisions that could place annual limitations on the future utilization of net operating loss carryforwards and credits in the event of a change in ownership of the Company, as defined.

We file income tax returns in the U.S. federal jurisdiction and several state jurisdictions. We currently have no tax examinations in progress. We also have not paid additional taxes, interest or penalties as a result of tax examinations nor do we have any unrecognized tax benefits for any of the periods in the accompanying financial statements.

The income tax provision consisted of the following:

	During the Years Ended December 31,	
	2020	**2019**
Current		
Federal	$—	$—
State	4,496	3,490
Current subtotal	4,496	3,490
Deferred		
Federal	(418,295)	(240,458)
State	(24,337)	(31,205)
Deferred subtotal, gross	(442,632)	(271,663)
Valuation allowance	428,000	296,347
Deferred subtotal, net	(14,632)	24,684
Income tax (benefit) expense	($10,136)	$28,174

The actual income tax expense differs from the expected tax computed by applying the U.S. federal corporate tax rate of 21% to the loss before income taxes during the years ended December 31, 2020 and 2019 respectively, as follows:

	During the Years Ended December 31,			
	2020		2019	
	$	%	$	%
Computed expected income tax expense rate	($216,773)	(21.00%)	($266,157)	(21.00%)
State income taxes, net of federal expense	(15,674)	(1.52)	(21,894)	(1.73)
Share-based compensation	30,121	2.92	37,811	2.98
Tax credits	(55,180)	(5.35)	(27,815)	(2.19)
Valuation allowance	428,000	41.46	296,347	23.38
Paycheck Protection Program loan forgiveness	(196,917)	(19.08)	—	—
Other	16,287	1.59	9,882	0.78
Income tax (benefit) expense/rate	($10,136)	(0.98%)	$28,174	2.22%

The significant components of our deferred tax assets, net, consisted of the following:

	As of December 31,	
	2020	2019
Product rights	$444	$6,709
Property, plant and equipment	(2,482,237)	(2,306,435)
Federal general business tax credits	490,018	434,838
Federal net operating loss carryforwards	3,074,882	2,509,471
State tax credits carryover	826,091	841,558
Interest rate swaps	—	14,632
Prepaid expenses and other	(8,814)	(12,070)
UNICAP	11,791	16,756
Incentive compensation	53,179	31,895
Valuation allowance	(1,965,354)	(1,537,354)
Deferred tax assets, net	$—	$—

17. SEGMENT INFORMATION

We principally operate in the business segment described in Note 1. Pursuant to Codification Topic 280, *Segment Reporting*, we operate in one reportable business segment, that being the development, acquisition, manufacture and sale of products that improve the health and productivity of dairy and beef cattle. Almost all of our internally funded product development expenses are in support of such products. The significant accounting policies of this segment are described in Note 2. Our single operating segment is defined as the component of our business for which financial information is available and evaluated regularly by our chief operating decision-maker in deciding how to allocate resources and in assessing performance. Our chief operating decision-maker is our President and CEO.

Sales of the **First Defense**® product line aggregated 98% and 97% of our total product sales during the years ended December 31, 2020 and 2019, respectively. Our primary customers for the majority of our product sales (89% during both of the years ended December 31, 2020 and 2019) are in the U.S. dairy and beef industries. Product sales to international customers, who are also in the dairy and beef industries, aggregated 11% and 10% of our total product sales during the years ended December 31, 2020 and 2019, respectively.

18. RELATED PARTY TRANSACTIONS

Dr. David S. Tomsche (Chair of our Board of Directors) is a controlling owner of Leedstone Inc., a domestic distributor of ImmuCell products (the **First Defense®** product line and **CMT**), and of J-t Enterprises of Melrose, Inc., an exporter. His affiliated companies purchased $668,308 and $490,323 of products from us during the year ended December 31, 2020 and 2019, respectively, on terms consistent with those offered to other distributors of similar status. We made marketing-related payments of $975 to these affiliated companies during the years ended December 31, 2020 and 2019, which represent amounts similar to those offered to other distributors of similar status. These payments are expensed as incurred. Our accounts receivable (subject to standard and customary payment terms) due from these affiliated companies aggregated $51,286 and $0 as of December 31, 2020 and 2019, respectively.

19. EMPLOYEE BENEFITS

We have a 401(k) savings plan (the Plan) in which all employees completing one month of service with the Company are eligible to participate. Participants may contribute up to the maximum amount allowed by the Internal Revenue Service. We currently match 100% of the first 3% of each employee's salary that is contributed to the Plan and 50% of the next 2% of each employee's salary that is contributed to the Plan. Under this matching plan, we paid $131,217 and $126,638 into the Plan for the years ended December 31, 2020 and 2019, respectively.

20. SUBSEQUENT EVENTS

We have evaluated subsequent events through the time of filing on March 30, 2021, the date we have issued this Annual Report on Form 10-K. As of the time of filing on March 30, 2021, there were no material, reportable subsequent events.

Signatures

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ImmuCell Corporation
Registrant

Date: March 30, 2021 By: /s/ Michael F. Brigham
Michael F. Brigham President, Chief Executive Officer and Principal Financial Officer

POWER OF ATTORNEY

We, the undersigned directors of ImmuCell Corporation, hereby severally constitute and appoint Michael F. Brigham our true and lawful attorney-in-fact and agent with full power of substitution and re-substitution, for us and in our stead, in any and all capacities, to sign any and all amendments to this report and all documents relating thereto, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing necessary or advisable to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or to be done by virtue hereof.

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Date March 24, 2021 By: /s/ Gloria J. Basse
Gloria J. Basse, Director

Date: March 24, 2021 By: /s/ Michael F. Brigham
Michael F. Brigham
President, Chief Executive Officer,
Principal Financial Officer and Director

Date: March 24, 2021 By: /s/ Bobbi Jo Brockmann
Bobbi Jo Brockmann, Vice President of Sales and Marketing and Director

Date: March 24, 2021 By: /s/ David S. Cunningham
David S. Cunningham, Director

Date: March 24, 2021 By: /s/ Steven T. Rosgen
Steven T. Rosgen, Director

Date: March 24, 2021 By: /s/ Jonathan E. Rothschild
Jonathan E. Rothschild, Director

Date: March 24, 2021 By: /s/ David S. Tomsche
David S. Tomsche, DVM, Director

Date: March 24, 2021 By: /s/ Paul R. Wainman
Paul R. Wainman, Director